Dynamic Rectus Abdominis Muscle Sphincter for Stomal Continence

Janou W.J.M. Bardoel

Bardoel, Janou Wilhelmina Johanna Maria
Dynamic Rectus Abdominis Muscle Sphincter for Stomal Continence - 2002
Thesis University of Utrecht

ISBN: 90-393-2997-4

Print: Budde Elinkwijk Grafische Producties, Nieuwegein
Design and Layout: MTM Grafische Studio, UMC Utrecht

The studies described in this thesis were financially supported by
a grant from the Alliant Community Trust Fund and a Mason and Rudd grant from the Jewish Hospital Foundation in Louisville, Kentucky, USA and grants from the Professor Michaël-van Vloten Fonds and the Stichting “De Drie Lichten” in The Netherlands

Publication of this thesis was financially supported by
AB Medical *prs* BV, Johnson & Johnson Medical, Mediprof, Ortomed BV, Smith & Nephew Hoofddorp, Van Straten Medical

Dynamic Rectus Abdominis Muscle Sphincter for Stomal Continence

Dynamische Musculus Rectus Abdominis Sfincter voor Stoma Continentie

(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor
aan de Universiteit Utrecht,
op gezag van Rector Magnificus, Prof. dr. W.H. Gispen
ingevolge het besluit van het College voor Promoties
in het openbaar te verdedigen
op dinsdag 23 april 2002 des middags te 4.15 uur

door

Janou W. J. M. Bardoel
geboren op 22 oktober 1971 te Venray

Promotor:
Moshe Kon, M.D., Ph.D., Professor and Head of the Division of Plastic, Reconstructive & Hand Surgery, University Medical Center, Utrecht, The Netherlands.

Co-promotores:
John H. Barker, M.D., Ph.D., Associate Professor of Surgery, Director of Plastic/Hand Surgery Research, University of Louisville, Louisville, Kentucky, USA.

Wayne K. Stadelmann, M.D., Associate Professor of Surgery, Division of Plastic and Reconstructive Surgery, Department of Surgery, University of Louisville, Louisville, Kentucky, USA.

To my mother, sister and friends from all over the world

Contents

Chapter 1

General Introduction

Some life-saving surgeries result in the necessity to establish permanent stomas; this outcome has an undeniable physical and emotional effect on the patient's life. For these patients the presence of the stoma and external pouching system may be lifelong reminders of the societal stigmas regarding elimination. The need to provide long-term physical and emotional support for many of these patients also has resulted in significant costs for the health care system. Although patients with permanent stomas reasonably adjust, complications that include peristomal skin irritation, pouching system dysfunction, stoma problems, renal deterioration (in patients with a urinary diversion), social inhibition, depression, and sexual dysfunction also have been reported.[1-10]

The underlying issue is continence: the ability to control and evacuate feces, flatus, or urine at socially acceptable times and places. In fecal incontinence the definition extends to being able to distinguish between gas and stool. Surgeries resulting in traditional abdominal stomas render the patient incontinent. The use of a pouching system provides a measure of continence or control over elimination. Even infrequent leakage and odor, however, are frank reminders of underlying incontinence. There remains a need to be continent. Research in this area also has been motivated by the prolonged survival of these patients. With operative survival routine and cure of cancer common, patients are living longer and therefore are willing to have a type of surgery that promises a more "natural" result. That is, patients no longer are universally grateful to be alive; they also seek an improved quality of life.

The quest for fecal continence has resulted in numerous non-surgical and surgical continent diversion techniques.[11-32] The use of dynamic myoplasty is one of them. Dynamic myoplasty is a term given to the use of electrical stimulation devices to stimulate surgically elevated muscle flaps. Using new electrical stimulation devices and skeletal muscle flaps dynamic myoplasty has been used to treat fecal[33] and urinary[34] incontinence using a gracilis muscle flap neo-sphincter. Another clinical example is use of the lattissimus dorsi muscle to augment the pump function of the heart in patients with chronic heart failure.[35] None of the attempted techniques to maintain stomal continence have enjoyed widespread use because of associated complications or because these techniques were not able to provide complete continence. Failure of the surgical techniques has been mainly due to foreign body related complications like wound infections or ischemic complications related to the surgical procedure.[24,25,36,37] These eventually lead to necrosis of the stoma and peristomal area[27,38] resulting in narrowing of the stoma. In dynamic myoplasty these complications should not occur since the stoma sphincter is constructed of innervated and vascularized autogenous skeletal muscle. However, like the many other attempts, the use of dynamic myoplasty to achieve stomal continence has also met with limited success. The results do not support dynamic myoplasty as being a better alternative treatment for fecal stomal incontinence than those methods already available. *Denervation* atrophy caused by flap elevation to construct the sphincter and early *muscle fatigue* caused by continuous electrical stimulation were responsible for these disappointing results and constitute the major obstacles standing in the way of dynamic myoplasty becoming an effective solution to stomal incontinence in the clinical setting.

Aim and outline of this thesis

Aim

The aim of this thesis was to create an abdominal stomal sphincter with an electrically stimulated skeletal muscle flap (dynamic myoplasty) in order to maintain long-term stomal continence.

The following questions were investigated in this thesis:

- Is it possible to use an innervated pedicled skeletal muscle flap, using local available skeletal muscle, for stomal sphincter construction?
- Which muscle flap design is the best for stomal sphincter construction while keeping its innervation intact?
- Is the developed muscle sphincter able to function as such, e.g. able to generate sphincter pressures that are consistent with stomal continence?
- Is it feasible to make the stomal sphincter fatigue-resistant by means of training resulting in long-term stomal continence?
- What type of electrical stimulation (intramuscular or direct nerve) is the best in terms of generating long-term stomal continence?
- What is the effect of chronic stimulation on the stomal sphincter muscle fiber type transformation, muscle fiber histology and its bowel wall morphology?

Outline

Based on previous reports on dynamic myoplasty for stomal incontinence and our laboratory success using dynamic myoplasty techniques[39-43] it was believed that a continent stoma sphincter could be designed and could provide continence for at least several hours. A multiphase project was undertaken that was designed to solve the critical issues of denervation atrophy and early muscle fatigue.

Chapter 2 describes the types of intestinal stomas, epidemiology of stomas, problems associated with stomas and it focuses on the problem of stomal incontinence. Past and current treatment options for stomal incontinence are outlined in detail in this chapter.

The phenomenon muscle plasticity, dynamic myoplasty and its clinical applications are described in **Chapter 3**. This is followed by description of the former attempts in applying dynamic myoplasty to the problem of stomal incontinence.

In **Chapter 4** the basic knowledge of physiologic and electrical muscle stimulation is described to better understand and approach the problems encountered with functional electrical stimulation (FES). The problem of muscle fatigue and methods of approaching it will be described in detail.

The first phase of our multiphase study is described in **Chapter 5**. This first study addressed the problem of denervation atrophy. It involved identifying an ideal muscle to use as a stomal sphincter and determining the anatomical feasibility of using that muscle to wrap around a fecal stoma in fresh human cadavers. Two different flap designs were investigated.
The second phase is described in **Chapter 6**. The proposed rectus abdominis muscle island flap design, developed in the first study, was attempted in an acute canine model. The aim of this study was to determine if the elevated flap wrapped around a stoma would function as such e.g. would be able to generate stomal pressures sufficient for stomal continence.
In order to solve the problem of muscle fatigue we performed two chronic canine studies (third and fourth phase). In the first chronic study we defined a methodology for training the muscle sphincter. This study was designed to determine if the rectus muscle could be “trained” to become fatigue resistant in a chronic canine model. In the first part of the chronic study (Part I. Intramuscular stimulation) we investigated two training protocols (A and B). The best was defined to be the one that led to stomal continence for a couple of hours. The second chronic study (Part II. Direct nerve stimulation) involved the application of the best training protocol found in Part I with the use of nerve cuff electrodes instead of intramuscular electrodes. These chronic studies are described in **Chapter 7**.
In **Chapter 8** the effect of chronic stimulation on sphincter muscle fiber type transformation and muscle fiber histology was analyzed. In addition the examination of the morphologic changes in the small bowel was investigated in this chapter.
Chapter 9 includes the summary and epilogue of this thesis.

References

1 MacDonald, L., and Anderson, H. Stigma in patients with rectal cancer: a community study. *J. Epidemiol. Community Health* 38: 284, 1984.

2 Bloom, D.A., Grossman, H.B., and Konnak, J.W. Stomal construction and reconsruction. *Urol. Clin. North. Am.* 13: 275, 1986.

3 Hurny, C., and Holland, J. Psychosocial sequelae of ostomies in cancer patients. *CA Cancer J. Clin.* 35: 170, 1985.

4 Coe, M., and Kluka, S. Concerns of clients and spouses regarding ostomy surgery for cancer. *J. Enterostom. Ther.* 15: 232, 1988.

5 Dyk, R.B., and Sutherland, A.M. Adaptation of the spouse and other family members to the colostomy patient. *Cancer* 9: 123, 1956.

6 Follick, M., Smith, T., and Turk, D. Psychosocial adjustment following ostomy. *Health Psychol.* 3: 505, 1984.

7 Kennedy, H.J. Quality of life in patients with an ileostomy. *Int. Disabil. Stud.* 10: 175, 1988.

8 Pernet, F.P.P.M., and Jonas, U. *World J. Urol* 3: 140, 1985.

9 Rolstad, B.S. Innovative surgical procedures and stoma care in the future. *Nurs. Clin. North. Am.* 22: 341, 1987.

10 Tucker, S.B., and Smith, D.B. Dermatologic Conditions Complicating Ostomy Care. In D.B. Smith, and D.E. Johnson (Eds.), *Ostomy Care and the Cancer Patient.* Orlando, FL: Grune & Stratton, 1986.

11 Gawron, C.L. Colostomy irrigations: mechanism guidelines. *Ostomy Wound Manage* 28: 56, 1990.

12 Burcharth, F., Ballan, A., Kylberg, F., and Rasmussen, S.N. The colostomy plug: a new disposable device for continent colostomy. *Lancet* 2: 1062, 1986.

13 Soliani, P., Carbognani, P., Piccolo, P., Sabbagh, R., and Cudazzo, E. Colostomy plug devices: a possible new approach to the problem of incontinence. *Dis. Colon Rectum* 35: 969, 1992.

14 Košorok, P. Colostomy tube: new device for a continent colostomy. *Dis. Colon Rectum* 38: 760, 1995.

15 Reboa, G., Frascio, M., Zanolla, R., Pitto, G., and Riboli, E.B. Biofeedback training to obtain continence in permanent colostomy. *Dis. Colon Rectum* 28: 419, 1985.

16 Ceulemans, G., and Van Baden, M. Continente colostomie. *Tijdschr. Gastroenterol.* 18: 286, 1975.

17 Kock, N.G. Intra-abdominal reservoir in patients with permanent ileostomy. *Arch. Surg.* 99: 223, 1969.

18 Beahrs, O.H., Bess, M.A., Beart, R.W., and Pemberton, J.H. Indwelling ileostomy valve device. *Am. J. Surg.* 141: 111, 1981.

19 Fendel, E.H., and Fazio, V.W. Construction of a continent ileostomy using a porcine aortic valve. A preliminary report. *Dis. Colon Rectum* 25: 21, 1982.

20 Orangio, G.R., Bronsther, B., Abrams, M., and Wise, L. A new type of continent ileostomy. Results of an animal study. *Dis. Colon Rectum* 27: 238, 1984.

21 Salmons, R., Bloch, P., and Loygue, J. Magnetic closure of a reservoir ileostomy. *Dis. Colon Rectum* 23: 242, 1980.

22 Bokey, L., and Fazio, V.W. The mesenteric sling technique. *Cleve. Clin. Q.* 45: 231,1978.

23 Barnett, W.O. New approaches for continent ostomy construction. *J. Miss. State Med. Assoc.* 28: 1, 1987.

24 Schmidt, E. The continent colostomy. *World J. Surg.* 6: 805, 1982.

25 Centeno Neto, A.A., Veyrac, M., Briand, D., Spiliotis, J., Saint-Aubert, B., and Joyeux, H. Autotransplantation of the pylorus sphincter at the terminal abdominal colostomy: experimental study in dogs. *Dis. Colon Rectum* 34: 874, 1991.

26 Feustel, H., and Hennig, G. Kontinente kolostomie durch magnetverschluss. *Dtsch. Med. Wochenschr.* 100: 1063, 1975.

27 Golligher, J.C., Lee, W.R., McMahon, M.J., and Pollard, M. The Erlangen magnetic device: the technique for use and results in 22 patients. *Br. J. Surg.* 64: 501, 1977.

28 Prager, E. The continent colostomy. *Dis. Colon Rectum* 27: 253, 1984.

29 Tenney, J.B., Eng, M., and Graney, M.J. The quest for continence: a morphologic survey of approaches to a continent colostomy. *Dis. Colon Rectum* 21: 522, 1978.

30 Gorfine, S.R., Bauer, J.J., Gelernt, I.M. Continent colostomies. In J.M. Makeigen, and P.A. Cataldo (Eds.), *Intestinal Stomas: Principles, Techniques and Management.* St Louis: Quality Medical Publishing, 1993. Pp. 180-184.

31 Roberts, D.J. The pursuit of colostomy continence. *J. Wound Ostomy Continence Nurs.* 24: 92, 1997.

32 Cavina, E., Seccia, M., and Evangelista, G. Neo-sphincter and neo-stomy. New surgical views for myoelectric stimulated continence. A clinical experience. Preliminary report. *Am. J. Proctol. Gastroenterol. Colon Rectal Surg.* 33: 16, 1982.

33 Williams, N.S., Hallan, R., Kroeze, T.H., and Watkins, E.S. Construction of a neorectum and neoanal sphincter following previous proctocolectomy. *Br. J. Surg.* 76: 1191, 1989.

34 Janknegt, R.A., Baeten, C.G.M.I., Weil, E.H.J., and Spaans F. Electrically stimulated gracilis sphincter for treatment of bladder sphincter incontinence. *Lancet* 340: 1129. 1992.

35 Carpentier, A., and Chachques, P.A. Myocardial substitution with a stimulated skeletal muscle: First successful clinical case. *Lancet* 1: 1267, 1985.

36 Kock, N.G. Present status of the continent ileostomy: surgical revision of the malfunctioning ileostomy. *Dis. Colon Rectum* 19: 200, 1976.

37 Gottlieb, L.M., and Handelsman, J.C. Treatment of outflow tract problems associated with continent ileostomy. *Dis. Colon Rectum* 34: 936, 1991.

38 Khubchandani, I.T., Trimpi, H.D., Sheets, J.A., Stasik, J.J., and Balcavage, C.A. The magnetic stoma device: a continent colostomy. *Dis. Colon Rectum* 24: 344, 1981.

39 Caroll, S.M., Heilman, S.J., Stremel, R.W., Tobin, G.R., and Barker, J.H. Vascular delay improves latissimus dorsi muscle perfusion and muscle function for use in cardiomyoplasty. *Plast. Reconstr. Surg.* 99: 1329, 1997.

40 Van Aalst, V.C., Werker, P.M.N., Stremel, R.W., et al. Electrically stimulated free-flap graciloplasty for urinary sphincter reconstruction: A new surgical procedure. *Plast. Reconstr. Surg.* 102: 84, 1998.

41 Palacio, M.M., van Aalst, V.C., Perez-Abadia, G.A., et al. Muscular urinary sphincter: electrically stimulated myoplasty for functional sphincter reconstruction. *J. Urol.* 160: 1867, 1998.

42 Zonnevijle E.D.H., Somia N.N., Stremel R.W., et al. Sequential segmental neuromuscular stimulation: an effective approach to enhance fatigue resistance. *Plast. Reconstr. Surg.* 105: 667, 2000.

43 Zonnevijlle, E.D.H., Somia, N.N. Perez-Abadia, et al. Three parameters optimizing closed loop control in sequential segmental neuromuscular stimulation. *Artif. Organs* 23: 388, 1999.

hoofdstuk 02 27-03-2002 11:00 Pagina 11

Chapter 2

Stomal Incontinence: Treatment Options

Introduction

An intestinal stoma or ostomy is a surgically created opening in the anterior abdominal wall that allows the passage of fecal material or urine from the intestines. There are two types of intestinal stomas. A colostomy is a connection of the colon to the skin of the abdominal wall. An ileostomy involves exteriorization of the ileum on the abdominal skin. A variety of clinical situations (neoplastic, congenital, traumatic, inflammatory and ischemic disorders of the intestinal tract) necessitate the surgical formation of an intestinal stoma. The most common indication for a colostomy is colorectal cancer. The indication for ileostomy construction is for patients who require removal of the entire colon, and usually the rectum, for inflammatory bowel disease either Crohn's disease or ulcerative colitis. There are an estimated 750 thousand persons with ostomies in the United States and 100 thousand ostomy operations are performed annually in the United States.[1] Worldwide the numbers are not insignificant either. For example in The Netherlands the prevalence of patients with a stoma is approximately 20 thousand and in the United Kingdom the prevalence of colostomy patients is 100 thousand.
The type and anatomical location of the stoma determines the frequency of effluent, nature of the effluent (the consistency, the odor, the presence of corrosive enzymes), and the care required in terms of pouching, or application of an external collection device. The physiology of the colon should be taken into account when considering the construction of a colostomy. The right side of the colon absorbs water and has irregular peristaltic contractions. Stomas made from the proximal half of the colon usually expel a liquid content. The left colon serves as a conduit and reservoir and has a few mass peristaltic motions per day. The content is more solid. A colostomy is usually located in the left lower quadrant. An alternative location is through the midline fascia. The surgical construction of an ileostomy must be more precise than for a colostomy because the content is liquid, high volume, and corrosive to the peristomal skin. An ileostomy is most of the time located in the right lower quadrant.
Individuals with stomas often have poor psychosocial outcomes that range from failure to return to occupation, withdrawal from social and intimate contact, to depression and anxiety.[2] Emotional and social withdrawal include feelings of degradation, damage, isolation, restriction, and mutilation. Embarrassment of the presence of an appliance or fear of leakage and odor may cause them to limit their social, sexual, recreational, and work activities. The lifelong stoma maintenance required by patients with permanent colostomies and ileostomies decreases the quality of life for many people.[3-7]

Because the stoma lacks a sphincter, elimination is not under the voluntary control of the individual. The presence of stool or urine on a plane of the body that may be visible (or at least detectable) to others during social contact poses a major concern to the person with a stoma. Involuntary passage of flatus, and the sound created by the passage, is also a major concern to the person with an intestinal stoma.
Many efforts have been done in the past to address the problem of stomal incontinence. Most current methods for stomal continence use an external pouching system (plastic bag reservoir) into which the fecal material or urine empties constantly and over which the patient has little or no control. These methods have many disadvantages such as a bulky, inconvenient external appliance filled with malodorous fluid that threatens to leak or cause odor and which may be associated with audible, embarrassing intestinal sounds. Through the years, multiple techniques have been proposed to improve the quality of life of these individuals by providing them with stomal continence.[8-10] These include nonsurgical and surgical techniques.

Nonsurgical Techniques

Nonsurgical techniques consist mainly of an irrigation technique or the use of devices that occlude the stoma when desired. The most frequently used non-surgical treatment option for patients with a distal colostomy is intermittent irrigation of the stoma to wash out formed stool.[11-14] The technique of irrigation uses a cone tip that fits into the stoma only enough to provide a seal and to allow the instillation of 500 to 1000 ml of water. Once the water has been instilled, a drainage bag is applied, and the colostomy empties in response to this stimulation. Between irrigations the patient usually wears a security pouch, which permits passage of gas through a filter. This is only recommended for colostomies of the distal colon where stool is more solid and well formed, and for patients who are physically and mentally capable of performing self-care. Another non-surgical strategy for continence is a disposable colostomy plug.[15,16] Success rates associated with the use of this plug have varied.[17,18] Recently a colostomy tube was developed, consisting of a silicone funnel and tube. Using a canine model, the funnel and tube were inserted in the bowel lumen after colostomy creation.[19] Although promising results were reported in these dog studies, clinical trials have not yet been published. Another option is behavior modification. This technique involves training patients to sense bowel evacuation and respond by contracting their abdominal muscles to close the stoma. Reboa *et al.* investigated biofeedback training to obtain continence in patients with a permanent colostomy.[20] Results were considered good when patients attained at least 70% continence. Of 18 patients investigated, 15 achieved said levels.

Surgical Techniques

Numerous surgical techniques have been designed to obtain stomal continence. Ceulemans and Van Baden developed a technique that involved positioning a very small colostomy as high as possible along the left costal margin of the rectus abdominis muscle.[21] This design was based on the idea that a stoma on the superior aspect of the abdominal wall would not drain stool in a dependent gravity-assisted fashion. Despite some reported success, this procedure has not gained widespread acceptance and is no longer performed.

Kock *et al*. developed an intestinal nipple valve by intussuscepting a segment of bowel that was interposed between a bowel reservoir and the stoma.[22] This procedure is used most often with ileostomies and in a few clinical cases in colostomies.[23] With this technique the patient no longer needs to wear an external appliance. However, intermittent intubation of the reservoir with a silicone catheter is still required to evacuate stool. Evacuation becomes difficult if the stool is allowed to become too thick. Complications of this latter technique are frequent and are due to dysfunction of the nipple valve. Nipple valve dysfunction is due to sliding or prolapse of the nipple valve, internal fistulae bypassing the valve or stomal strictures.[24-26] Concurrently, complete replacement of the valve by various prosthetic mechanisms was under investigation. Beahrs *et al.* found that a cuffed Silastic catheter, similar to an endotracheal tube, restored continence in “failed” Kock ileostomies.[27] Fendel and Fazio replaced the nipple valve by a porcine aortic valve in an experimental model.[28] A mucosal “flap” valve was created in another experimental setting.[29] Magnetic closing caps were implanted successfully in two patients[30] Although the devices subjected to clinical trials were able to maintain continence, various complications and limited patient acceptance prevented widespread adoption of their use. A different approach was taken by Fazio, Cohen, Barnett, and others. They found that the intussuscepted nipple valve was more stable when it was mechanically supported at its junction with the pouch and the outflow tract. A strip of fascia,[31] Marlex or Prolene,[32] and later, an ileal limb[33] were used to buttress the valve. Short-term results were promising. A dramatic decrease in the rate of valve desusception was reported. However, an equally dramatic rise in the rate of late fistula formation was associated with the use of the various plastic materials.[34,35]

Another surgical technique designed to create a continent stoma involved construction of a sphincter using a smooth muscle graft of the large intestine.[36] The transplanted smooth muscle was wrapped around the distal portion of the intestine and the intestine with its new smooth muscle coat was brought through the abdominal wall as a stoma. In a series of nearly 500 patients, almost 80% were able to go for a 24-hour period without the need for an appliance. Continence of liquid stools and gas, however, was not sustained and postoperative complications ultimately led to the abandonment of this procedure. Autotransplantation of the stomach pyloric sphincter muscle around the colon has been attempted in a canine model. However, narrowing of the neo-sphincter produced obstruction and fecal continence was not achieved.[37] Artificial sphincters in the form of implanted devices are another surgical treatment option. A magnetic stoma mechanism was introduced by Feustel and Hennig[38] and described by Kubchandani and coworkers.[39] The system consisted of a magnetic ring implanted subcutaneously in the abdominal wall. The bowel was brought through the ring and a stoma was created. After a recovery period, the magnetic external cap was inserted into the stoma. Complete continence varied from 23% to 76% of the patients in different clinical trials. Complications with this procedure varied in terms of severity[40] and included wound infections, necrosis of the stoma and peristomal area, development of fistulae, and incontinence due to suboptimal seating of the internal magnetic ring. A two-part silicone device was developed by Prager *et al.*,[41] but complications were similar to those encountered with the magnetic device.

Last but not least dynamic myoplasty has been attempted as one of the surgical techniques to generate stomal continence.[42-44] Dynamic myoplasty uses own skeletal muscle and therefore prevents foreign body related complications at the level of the stoma.

References

1 Hurny, C., and Holland, J. Psychosocial sequelae of ostomies in cancer patients. *CA Cancer J. Clin.* 35: 170, 1985.
2 MacDonald, L. and Anderson, H. Stigma in patients with rectal cancer: a community study. *J. Epidemiol. Community Health* 38: 284, 1984.
3 Rolstad, B., Wilson, G., and Rothenberger, D.A. Sexual concerns in the patient with an ileostomy. *Dis. Colon Rectum* 26:170, 1983.
4 Keltikangas-Järvinen, L., Loven, E., and Möller, C. Psychic factors determining the long-term adaptation of colostomy and ileostomy patients. *Psychother. Psychosom.* 41: 153, 1984.
5 Kelman, G., and Minkler, P. An investigation of quality of life and self-esteem among individuals with ostomies. *J. Enterostom. Ther.*16: 11, 1989.
6 Klopp, A.L. Body image and self-concept among individuals with stoma's. *J Enterostom. Ther.* 17: 98, 1990.
7 Bryant, R.A., and Hampton, B.G. *Ostomies and continent diversions: nursing management.* St Louis: Mosby-Year Book, 1992.
8 Tenney, J.B., Eng, M., and Graney, M.J. The quest for continence: a morphologic survey of approaches to a continent colostomy. *Dis. Colon Rectum* 21: 522, 1978.
9 Gorfine, S.R., Bauer, J.J., Gelernt, I.M. Continent colostomies. In: Makeigen JM, Cataldo PA, editors. *Intestinal stomas: principles, techniques and management.* St Louis: Quality Medical Publishing, 180-184, 1993.
10 Roberts, D.J. The pursuit of colostomy continence. *J. Wound Ostomy Continence Nurs.* 24: 92, 1997.
11 Terranova, O., Sandel F., Rebuffat, C., Maruotti, R., and Bortolozzi, E. Irrigation vs. natural evacuation of left colostomy: a comparitive study of 340 patients. *Dis. Colon Rectum* 22: 31, 1979.
12 Williams, N.S., and Johnston, D. Prospective controlled trial comparing colostomy irrigation with "spontaneous-action" method. *Br. Med. J.* 281: 107, 1980.
13 Doran, J., and Hardcastle, J.D. A controlled trial of colostomy management by natural evacuation, irrigation and foam enema. *Br. J. Surg.* 68: 731, 1981.
14 Gawron, C.L. Colostomy irrigations: mechanism guidelines. *Ostomy Wound Manage* 28: 56, 1990.
15 Cazador, A.C., Piñol, M., Rague, J.M., Montana, J., Nogueras, F.M., and Suñol, J. Multicenter study of a continent colostomy plug. *Br. J. Surg.* 80: 930, 1993.
16 Burcharth, F., Ballan, A., Kylberg, F., and Rasmussen, S.N. The colostomy plug: a new disposable device for continent colostomy. *Lancet* 2: 1062, 1986.
17 Clague, M.B., Heald, R.J. Achievement of stomal continence in one-third of colostomies by use of a new disposable plug. *Surg. Gynecol. Obstet.* 170: 390, 1990.
18 Soliani, P., Carbognani, P., Piccolo, P., Sabbagh, R., and Cudazzo, E. Colostomy plug devices: a possible new approach to the problem of incontinence. *Dis. Colon Rectum* 35: 969, 1992.
19 Košorok, P. Colostomy tube: new device for a continent colostomy. *Dis. Colon Rectum* 38: 760, 1995.

20 Reboa, G., Frascio, M., Zanolla, R., Pitto, G., and Riboli, E.B. Biofeedback training to obtain continence in permanent colostomy. *Dis. Colon Rectum* 28: 419, 1985.
21 Ceulemans, G., and Van Baden, M. Continente colostomie. *Tijdschr. Gastroenterol.* 18: 286, 1975.
22 Kock, N.G. Intra-abdominal reservoir in patients with permanent ileostomy. *Arch. Surg.* 99: 223, 1969.
23 Kock, N.G., Myrvold, H.E., Philipson, B.M., Svaninger, G, and Öjerskog, B. Continent cecostomy. *Dis. Colon Rectum* 28: 705, 1985.
24 Kock, N.G. Present Status of the continent ileostomy: surgical revision of the malfunctioning ileostomy. *Dis. Colon Rectum* 19: 200, 1976.
25 Kock, N.G., Myrvold, H.E., Nilsson, L.O., and Ahren, C. Construction of a stable nipple valve for the continent ileostomy. *Ann. Chir. Gynaecol.* 69: 132, 1980.
26 Gottlieb, L.M., Handelsman, J.C. Treatment of outflow tract problems associated with continent ileostomy. *Dis. Colon Rectum* 34: 936, 1991.
27 Beahrs, O.H., Bess, M.A., Beart, R.W., and Pemberton, J.H. Indwelling ileostomy valve device. *Am. J. Surg.* 141: 111, 1981.
28 Fendel, E.H., and Fazio, V.W., Construction of a continent ileostomy using a porcine aortic valve. A preliminary report. *Dis. Colon Rectum* 25: 21, 1982.
29 Orangio, G.R., Bronsther, B., Abrams, M., and Wise, L. A new type of continent ileostomy. Results of an animal study. *Dis. Colon Rectum* 27: 238, 1984.
30 Salmons, R., Bloch, P. and Loygue, J. Magnetic closure of a reservoir ileostomy. *Dis. Colon Rectum* 23: 242, 1980.
31 Bokey, L., and Fazio, V.W. The mesenteric sling technique. *Cleve. Clin. Q.* 45: 231, 1978.
32 Cohen, Z. Evolution of the Kock continent reservoir ileostomy. *Can. J. Surg.* 25: 509, 1982.
33 Barnett, W.O. New approaches for continent ostomy construction. *J. Miss. State Med. Assoc.* 28: 1, 1987.
34 Thompson, J.S., and Williams, S.M. Fistula following continent ileostomy. *Dis. Colon Rectum* 27: 193, 1984.
35 Cohen, Z. Current status of the continent ileostomy. *Can. J. Surg.* 30: 357, 1987.
36 Schmidt, E. The continent colostomy. *World J. Surg.* 6: 805, 1982.
37 Centeno Neto, A.A., Veyrac, M., Briand, D., Spiliotis, J., Saint-Aubert, B., and Joyeux, H. Autotransplantation of the pylorus sphincter at the terminal abdominal colostomy: experimental study in dogs. *Dis. Colon Rectum* 34: 874, 1991.
38 Feustel, H., and Hennig, G. Kontinente kolostomie durch magnetverschluss. *Dtsch. Med. Wochenschr.* 100: 1063, 1975.
39 Khubchandani, I.T., Trimpi, H.D., Sheets, J.A., Stasik, J.J., and Balcavage, C.A. The magnetic stoma device: a continent colostomy. *Dis. Colon Rectum* 24: 344, 1981.
40 Golligher, J.C., Lee, W.R., McMahon, M.J., and Pollard, M. The Erlangen magnetic device: the technique for use and results in 22 patients. *Br. J. Surg.* 64: 501, 1977.
41 Prager, E. The continent colostomy. *Dis. Colon Rectum* 27: 253, 1984.

42 Merrell, J.C., Russell, R.C., and Zook, E.G. Free microneurovascular gracilis muscle transfer in the dog for enterostomal sphincter construction and control: an experimental study. *Ann. Plast. Surg.* 17: 82, 1986.

43 Konsten, J., Baeten, C.G.M.I., van Mameren, H., Havenith, M.G., and Soeters, P.B. Feasibility of stoma continence, using electrically stimulated rectus abdominis muscle in pigs. *Dis. Colon Rectum* 36: 247, 1993.

44 Cavina, E., Seccia, M., and Evangelista, G. Neo-sphincter and neo-stomy. New surgical views for myoelectric stimulated continence. A clinical experience. Preliminary report. *Am. J. Proctol. Gastroenterol. Colon Rectal Surg.* 33: 16, 1982.

Chapter 3

Dynamic Myoplasty

Introduction

Myoplasty encompasses a variety of clinical processes involving transfer of skeletal muscle for replacement or enhancement of body parts. Depending on whether the purpose of using the skeletal muscle flap is for filling a defect or restoration of contractile function, innervation is not, respectively is of major importance.

Muscle flaps are mainly used for bulk to cover defects of the upper and lower extremity caused by trauma[1] and osteomyelitis,[2,3] deformities of the face[4] and to cover defects caused by oncological resections.[5] For breast reconstruction the rectus abdominis muscle has been used extensively. For this application the muscle serves as a carrier for the vascular supply but nowadays can be omitted when the vessels are dissected out (perforator flaps).[6] The result is an inferior epigastric artery skin flap without rectus abdominis muscle.

Restoration of upper and lower extremity function is made possible by transposition of tendons (local muscle flaps), transposition of distant pedicle muscle flaps and by microneurovascular reanastomoses in free muscle flaps. Restoration of function of the upper extremity by a gracilis muscle free flap for replacement of the flexor muscles of the forearm is an example.[7,8] Restoration of function using a distant pedicle flap has been described by Mackinnon *et al*. They transposed the latissimus dorsi muscle to the upper arm to replace a non-functioning biceps femoris.[9] As free revascularized muscle flaps the gracilis[10,11] and pectoralis minor muscle[12,13] have been used for dynamic reanimation in patients with facial paralysis. Restoration of function could be established after a microneurovascular anastomosis. In the given functional myoplasty examples the contraction characteristics of the transposed muscle flap are in close proximity to the original muscle (extremity musculature) or far from the normal function (face musculature) but no electrical stimulation is required because of reinnervation.

In the eighties there was felt to be a need for muscle flaps that could be more versatile in terms of performing a different function from its original one. This led to the development of *dynamic myoplasty*, in which the addition of electrical stimulation allows the transferred skeletal muscle to provide a function different from its original one. The two major applications presently under clinical investigation are dynamic cardiomyoplasty for the treatment of heart failure and dynamic myoplasty for the treatment of fecal or urinary incontinence (dynamic anal respectively urinary graciloplasty).

Muscle Plasticity

The term muscle 'plasticity' refers to the ability of muscle tissue to undergo profound changes in its contractile speed and other properties long after the primary processes of differentiation and growth have been completed. The contractile properties of muscle can be changed by exercise and electrically induced exercise. The latter involves the placement of an electrode in a muscle or on a nerve followed by a conditioning period of electrically induced exercise. During this period the muscle is subjected to continuous or interrupted electrical stimulation in a graded incremental fashion until the desired properties are achieved. The effect of exercise is to convert the muscle from one that fatigues rapidly (fast-twitch glycolytic (type II) fibers) to one that can sustain a reasonable force for a protracted period of time (slow-twitch oxidative (type I) fibers).

From animal experimentation it is known that continuous stimulation, at a low frequency (5-10 Hz), can convert a muscle with a mixed fiber type population to a muscle with a uniform population of slow-twitch fibers, which have a high capacity for oxidative metabolism.[14-17] It is also known that a muscle subjected to electrically induced exercise with a low frequency (10 Hz) paradigm will undergo a decrease in mass and a decrease in the magnitude of the maximum force the muscle can generate.[18,19] Muscle property changes can be predicted and fashioned for a particular purpose, depending on the stimulation paradigm involved. Hudlicka *et al*. found that a paradigm that allowed the muscle to generate greater sustained muscle tension was the 30 Hz pattern. Muscles adapted to a particular paradigm functioned more effectively in concert with that paradigm. However, histochemical, histological, and biochemical results did not explain the different effects of the stimulation paradigms. No difference was found in the extent of fiber conversion present for muscles stimulated at 10 and 30 Hz in the same animal despite the improvement in sustained and tetanic tension seen for muscles stimulated at 30 Hz.[20] Changes in muscle properties have been mainly attributed to the total hours of stimulation per day and not the pattern of stimulation.[20,21]

Dynamic Cardiomyoplasty

Dynamic Cardiomyoplasty is a technique that uses skeletal muscle to augment ventricular function.[22-24] It is aimed at treating patients with chronic heart failure, refractory to medical therapy, that severely limits their daily life, a Class III or intermittent Class IV condition, according to the New York Heart Association (NYHA) classification.[25] In dynamic cardiomyoplasty, the latissimus dorsi muscle is elevated as a flap based on its thoracodorsal neurovascular pedicle, transferred into the thorax, and wrapped around the ventricles of a failing heart. The most common form of the procedure involves wrapping the left latissimus dorsi muscle around the heart as a posterior wrap.[26] Subsequently, the muscle is trained over an 8-12 week period to contract in synchrony with cardiac systole by means of a programmable, implantable nerve-muscle stimulator.[27,28] In this way, cardiac function is augmented. The first procedure was performed in 1985 in Paris by Carpentier *et al*.[29] and to date has been performed clinically in more than 600 patients worldwide.

Whilst many patients do well after cardiomyoplasty procedures in the literature there exists a large variability in the actual improvements in cardiac haemodynamic indices described.[30,31] The reason for this variability is unclear. One of the possibilities could be related to the viability of the latissimus dorsi muscle used to wrap the heart. It is known that when the latissimus dorsi muscle is lifted in its entirety on its thoracodorsal pedicle the distal region of the flap will experience ischemia and often go on to necrosis.[32] In experimental studies vascular delay has been found to improve latissimus dorsi muscle perfusion and contractile function.[33,34]

Another determining factor of the functional outcome could be the training protocol used. Different methods of electrical stimulation have been compared in their effectiveness of creating fatigue resistance[35] and their effect on damaging the muscle.[36] Chronic electrical training of the latissimus dorsi muscle prior to cardiomyoplasty has been studied in various experimental models. Mannion *et al*. examined chronic electrical stimulation and vascular delay as done before cardiomyoplasty. They demonstrated that, after mobilizing the latissimus dorsi, chronic electrical preconditioning of the latissimus dorsi muscle prior to cardiomyoplasty significantly increased, but did not totally restore, exercise-induced blood flow to the distal part of the muscle when compared to contralateral in situ latissimus dorsi muscle.[37] Ali *et al*. found that preconditioning the latissimus dorsi muscle with vascular delay resulted in improving performance of the latissimus dorsi muscle with consistent increases in left ventricular hemodynamics. However, this was not observed after preconditioning with chronic electrical stimulation.[38]

Dynamic Anal Graciloplasty

Fecal incontinence is an underreported condition that affects 2.5 percent of the population. It is a huge problem in human terms with high direct economic costs and indirect costs that result from the unwillingness of people to leave their homes. If anal sphincter repair or biofeedback training is not successful, dynamic graciloplasty is an effective option.

In the 1950s, surgeons developed a passive wrap of gracilis muscle around the anal canal.[39,40] It failed because the patients were unable to maintain the necessary contraction of the muscle voluntarily because the muscle fatigued. The electrically stimulated, skeletal muscle neo-sphincter was developed later on. It adds to the passive muscle wrap a neural or intramuscular electrode that stimulates the muscle.[41,42] An electrical stimulation protocol lasting eight weeks is used to transform the muscle into a fatigue-resistant fiber type. During this period the muscle is stimulated using a graded incremental training regimen until continuous stimulation is achieved. The patient controls fecal continence at will by turning an electrical stimulating device on and off to open and close the skeletal muscle neo-sphincter. Widespread applicability of the procedure was limited initially by the need for an external stimulator. Technological advances in the field of electronics have made available electrical stimulation devices that are small, implantable and have long battery lives.

In 1988, Baeten *et al*. reported the implantation of a neuromuscular stimulator in a patient who had been treated previously with a gracilis muscle transposition because of anal atresia. This resulted in a perfectly controllable sphincter function.[43] In 1989, Williams *et al*. reported a case of construction of a neoanal sphincter following proctectomy.[44] In 1991, Williams *et al*. then described the use of a neoanal sphincter in 20 patients with fecal incontinence.[42] Although there were six failures, the results were encouraging because in all patients with functioning neo-sphincters, continence was improved. Complications included severe perineal sepsis in nine patients, including muscle necrosis in four, electrode displacement in four, difficult evacuation in four, fibrosis and stricture in two, and transient neuralgia in two. This high complication rate must be taken in context with the fact that the only other option for these patients was a permanent stoma.

Vascular delay of the gracilis muscle is described as a possible solution to improve blood supply in the distal part of the gracilis muscle.[45] This concept was applied by Williams *et al*.[42] and Wexner *et al*.[46] To prevent ischemia of the distal part of the gracilis muscle vascular delay 4-6 weeks before transposition of the gracilis muscle was used. It was suggested that improvement of the results was attributable to vascular delay prior to muscle transposition. However, Williams *et al*. reported later on elimination of the delay without adverse effects.[47]

So far no randomized study has been performed to explore whether the final result depends on the type of loop used to wrap the gracilis muscle around the anal canal. Good results have been reported with the gamma loop,[41] the epsilon loop,[42] the alpha loop[48] and the modified epsilon loop.[49]

Dynamic Urinary Graciloplasty

Deming was the first to describe the graciloplasty for urinary incontinence in 1926.[50] In a population of children with total incontinence because of epispadia, he detached the gracilis muscle at its insertion under the knee and wrapped it around the urethra. While pressing the knees tightly against each other by activating the adductors, including the gracilis muscle, the patients could actively evoke urinary continence. In 1956 Pickrell *et al*. reported the same procedure in a series of patients as a success.[51] However, the drawback of this technique was that it is not possible to maintain continence for a long time, because of muscle fatigue. The success of the anal dynamic graciloplasty for treating fecal incontinence led some investigators to explore a similar approach to restoring urinary incontinence. Janknegt *et al*.[52] and Williams *et al*.[53] reported use of the same procedure with the addition of an implantable stimulator to electrically stimulate the gracilis muscle flap. Despite the promising potential of this new application of dynamic myoplasty, preliminary outcomes have been disappointing. The main problems seemed to be associated with stricture of the urethra created by the neosphincter as a result of distal muscle ischemia.[53,54] In an experimental study van Aalst *et al*. addressed this problem by introducing a new procedure whereby the gracilis muscle is used as a free flap by dividing the main vascular pedicle and the muscle's origin at the pubic bone and reanastomose its vascular supply.[55] The well-vascularized proximal part of the gracilis flap could now be used to form the neo-sphincter and showed no evidence of stricture of the urethra for a follow-up of 16 weeks.[56]

Dynamic Myoplasty for Stomal Incontinence

A new, and yet to be clinically tested, option for stomal incontinence is the use of dynamic myoplasty. To date, few studies have been done to investigate the feasibility of using dynamic myoplasty to provide stomal continence. The few reported cases done have been discouraging. Cavina *et al*.[57] electrically stimulated the internal oblique muscle in an attempt to create a continent stoma. However, only one patient was treated using this technique and no follow up has been reported. Merrel *et al*.[58] reported two different methods of using a free microneurovascular gracilis muscle flap in a dog model for stoma neo-sphincter construction. However, in both cases denervation atrophy of the gracilis flap (fatigue in one and closure of the stomal orifice in the other) was reported to have lead to failure. Konsten *et al*.[59] used electrically stimulated rectus abdominis muscle flaps in the pig. They described three different designs of using the rectus abdominis muscle for stoma sphincter construction. The first design was the proximal rectus abdominis muscle wrapped around the stoma. The second design was bowel pulled through the middle of the rectus abdominis muscle. Finally a sling was constructed using the distal part of the rectus abdominis muscle. They found that muscle denervation and fatigue lead to failure.

References

1 Zukowski, M., Lord, J., Ash, K., Shouse, B., Getz, S., and Robb, G. The gracilis free flap revisited: a review of 25 cases of transfer to traumatic extremity wounds. *Ann. Plast. Surg.* 40: 141, 1998.

2 Mathes S.J., Feng I.J., Hunt T.K. Coverage of the infected wound. *Ann. Surg.* 198: 420, 1983.

3 May J.W.Jr., Gallico G.C., Lukash F.N. Microvascular transfer of free tissue for closure of bone wounds of the distal lower extremity. *N. Engl. J. Med.* 306: 256, 1982.

4 Siebert, J.W., Anson, G., and Longaker, M.T. Microsurgical correction of facial asymmetry in 60 consecutive cases. *Plast. Reconstr. Surg.* 97: 354, 1996.

5 Janevicius, R.V. and Greager, J.A. The extensor carpi radialis longus muscle flap for anterior elbow coverage. *J. Hand Surg.* 17: 102, 1992.

6 Koshima, I., Moriguchi, T., Soeda, S., Tanaka, H. and Umeda, N. Free thin paraumbilical perforator-based flaps. *Ann. Plast. Surg*. 29: 12, 1992.

7 Krimmer, H., van Schoonhoven, J., and Lanz, U. Transplantation of the M. gracilis in the reconstruction of hand function. *Orthopade* 27: 445, 1998.

8 Manktelow, R.T., and Zuker, R.M. The principles of functioning muscle transplantation: Applications to the upper arm. *Ann. Plast. Surg.* 22: 275, 1989.

9 Mackinnon, S.E., Weiland, A.J., and Godina, M. Immediate forearm reconstruction with a functional latissimus dorsi island pedicle myocutaneous flap. *Plast. Reconstr. Surg.* 71: 706, 1983.

10 Harii, K., Ohmori, K., and Torii, S. Free gracilis muscle transplantation with microneurovascular anastomoses for the treatment of facial paralysis. *Plast. Reconstr. Surg.* 57: 133, 1976.

11 O'Brien, B.McC., Franklin, J.D., and Morrison, W.A. Cross-facial nerve grafts and microneurovascular free muscle transfer for long established facial palsy. *Br. J. Plast. Surg.* 33: 202, 1980.

12 Terzis, J.K. Pectoralis minor: a unique muscle for correction of facial palsy. *Plast. Reconstr. Surg.* 83: 767, 1989.

13 Harrison, D.H. The pectoralis minor vascularized muscle graft for the treatment of unilateral facial palsy. *Plast. Reconstr. Surg.* 75: 206, 1985.

14 Heilmann, C., Pette, D. Molecular transformation in sarcoplasmic reticulum of fast-twitch muscle by electro-stimulation. *Eur. J. Biochem.* 93: 437, 1979.

15 Pette, D., Ramirez, B.U., Müller, W., Simon, R., Exner, G.U., and Hildebrand, R. Influence of intermittent long-term stimulation on contractile, histochemical and metabolic properties in fast and slow rabbit muscles. *Pflügers Arch.* 361: 1, 1975.

16 Pette, D., Smith, M.E., Staudte, H.W., and Vrbova, G. Effects of long-term electrical stimulation on some contractile and metabolic characteristics of fast rabbit muscles. *Pflügers Arch.* 338: 257, 1973.

17 Salmons, S., Sreter, F.A. Significance of impulse activity in the transformation of skeletal muscle type. *Nature Lond.* 263: 30, 1976.

18 Hudlicka, O., Tyler, K.R., Srihari, T., Heilig, A., and Pette, D. The effect of different patterns of long-term stimulation on contractile properties and myosin light chains in rabbit fast muscles. *Pflügers Arch.* 393: 164, 1982.

19 Kwong, W.H., and Vrbova, G. Effects of low-frequency electrical stimulation on fast and slow muscles of the rat. *Pflügers Arch.* 391: 200, 1981.

20 Hudlicka, O., and Tyler, K.R. Importance of different patterns of frequency in the development of contractile properties and histochemical characteristics of fast skeletal muscle. *J. Physiol. Lond.* 301: 10P, 1979.

21 Aitman, T.J., Hudlicka, O., and Tyler, K.R. Long-term effects of tetanic stimulation on blood flow, metabolism and performance of fast skeletal muscles. *J. Physiol. Lond.* 295: 36P, 1979.

22 Chachques, J.C., Grandjean, P.A., Tommasi, J.J., Perier, P., Chauvaud, S., Bourgeois, I., and Carpentier, A. Dynamic cardiomyoplasty: a new approach to assist chronic myocardial failure. *Life Support Syst.* 5: 323, 1987.

23 Magovern, G.J. Introduction to the history and development of skeletal muscle plasticity and its clinical application to cardiomyoplasty and skeletal muscle ventricle. *Seminars in Thorac. & Cardiovasc. Surg.* 3: 95, 1991.

24 Carpentier, A., Chachques, J.C., Acar, C., Relland, J., Mihaileanu, S., Bensasson, D., Kieffer, J.P., Guibourt P, Tournay, D., Roussin, I, et al. Dynamic cardiomyoplasty at seven years. *J. Thorac. Cardiovasc. Surg.* 106: 42, 1993.

25 Carpentier, A., Chachques, P.A., Grandjean, P.A., eds. Cardiomyoplasty. *Mount Kisco, NY: Futura Publishing,* 1991.

26 Furnary, A.P., Chachques, J.C., Moreira, L.F.P., Grunkemeier, G.L., Swanson, J.S., Stolf, N., Haydar, S., Acar, C., Starr, A., Jatene, A.D., and Carpentier, A.F. Long-term outcome, survival analysis, and risk stratification of dynamic cardiomyoplasty. *J. Thorac. Cardiovasc. Surg.* 112: 1640, 1996.

27 Chachques, J.C., Grandjean, P.A., and Carpentier, A. Latissimus dorsi dynamic cardiomyoplasty. *Ann. Thorac. Surg.* 47: 600, 1989.

28 Chiu, R. Dynamic cardiomyoplasty for heart failure. *Br. Heart J.* 73: 1, 1995.

29 Carpentier, A., and Chachques, P.A. Myocardial substitution with a stimulated skeletal muscle: First successful clinical case. *Lancet* 1: 1267, 1985.

30 Hooper, T.L., and Salmons, S. Skeletal muscle assistance in heart failure. *Cardiovasc. Res.* 27: 1404, 1993.

31 Furnary, A.P., Magovern, J.A., Christlieb, I.Y., Orie, J.E., Simpson, K.A., and Magovern, G.J. Clinical cardiomyoplasty: preoperative factors associated with outcome. *Ann. Thorac. Surg.* 54: 1139, 1992.

32 Kratz, J.M., Johnson, W.S., Mukherjee, R., Hu, J., Crawford, F.A., and Spinale, F.G. The relation between latissimus dorsi skeletal muscle structure and contractile function after cardiomyoplasty. *J. Thorac. Cardiovasc. Surg.* 107: 868, 1994.

33 Carroll, S.M., Heilman, S., Stremel, R.W., Tobin, G.R., and Barker, J.H. Vascular delay improves latissimus dorsi muscle perfusion and muscle function for use in cardiomyoplasty. *Plast. Reconstr. Surg.* 99: 1329, 1997.

34 Ali, A.T., Santamore, W.P., Chiang, B.Y., Dowling, R.D., Tobin, G.R., and Slater, A.D. Vascular delay of the latissimus dorsi provides an early hemodynamic benefit in dynamic cardiomyoplasty. *Ann. Thorac. Surg.* 67: 1304, 1999.

35 Badylak, S.F., Hinds, M., and Geddes, L.A. Comparison of three methods of electrical stimulation for converting skeletal muscle to a fatigue resistant power source suitable for cardiac assistance. *Ann. Biomed. Eng.* 18: 239, 1990.

36. Ianuzzo, C.D., Ianuzzo, S.E., and Anderson, W.A. Cardiomyoplasty: transformation of the assisting muscle using intermittent versus continuous stimulation. *J. Card. Surg.* 11: 293, 1996.

37 Mannion, J.D., Velchik, M., Hammond, R., Alavi, A., Mackler, T., Duckett, S., Staum, M., Hurwitz, S., Brown, W., and Stephenson, L.W. Effects of collateral blood vessel ligation and electrical conditioning on blood flow in dog latissimus dorsi muscle. *J. Surg. Res.* 47: 332, 1989.

38 Ali, A.T., Chiang, B.Y., Santamore, W.P., Dowling, R.D, and Slater, A.D. Preconditioning of the latissimus dorsi muscle in cardiomyoplasty: vascular delay or chronic electrical stimulation. *Eur. J. Cardiothorac. Surg.* 14: 304, 1998.

39 Pickrell, K.L., Broadbent, T.R., Masters, F.W., and Metzger, J.T. Construction of a rectal sphincter and restoration of anal continence by transplanting the gracilis muscle: a report of four cases in children. *Ann. Surg.* 135: 853, 1952.

40 Pickrell, K.L., Masters, F.W., Georgiade, N., and Horton, C. Rectal sphincter reconstruction using gracilis muscle transplant. *Plast. Reconstr. Surg.* 13: 46, 1954.

41 Baeten, C.G.M.I., Geerdes, B.P., Adang, E.M.M., et al. Anal dynamic graciloplasty in the treatment of intractable fecal incontinence. *N. Engl. J. Med.* 332: 1600, 1995.

42 Williams, N.S., Patel, J., George, B.D., et al. Development of an electrically stimulated neoanal sphincter. *Lancet* 338: 1166, 1991.

43 Baeten, C., Spaans, F., and Fluks, A. An implanted neuro muscular stimulator for fecal incontinence following previously implanted gracilis muscle: report of a case. *Dis Colon Rectum* 31: 134, 1988.

44 Williams, N.S., Hallan, R.I., Koeze, T.H., and Watkins, E.S. Construction of a neorectum and neoanal sphincter following previous proctocolectomy. *Br. J. Surg.* 76: 1191, 1989.

45 Patel, J., Shanahan, D., Riches, D.J., Sinnatamby, C.S., Williams, N.S., and Watkins, E.S. The arterial anatomy and surgical relevance of the human gracilis muscle. *J. Anat.* 176: 270, 1991.

46 Wexner, S.D., Gonzalez-Padron, A., Rius, J., et al. Stimulated gracilis neosphincter operation. Initial experience, pitfalls, and complications. *Dis. Colon Rectum* 39: 957, 1996.

47 Williams, N.S. The stimulated gracilis neosphincter. Presented at the annual meeting of the American society of colon and rectal surgeons, Montreal, Quebec, Canada, May 7-12, 1995.

48 Cavina, E., Seccia, M., and Evangelista, G. Perineal colostomy and electrostimulated gracilis 'neosphincter' after abdomino-perineal resection of the colon and anorectum: a surgical experience and follow-up study in 47 cases. *Int. J. Colorectal Dis.* 5: 6, 1990.

49 Rosen, H.R., Feil, W., Novi, G., Zoch, G., Dahlberg, S., and Schiessel, R. The electrically stimulated (dynamic) graciloplasty for faecal incontinence - first experience with a modified muscle sling. *Int. J. Colorectal Dis.* 9: 184, 1994.

50 Deming, C.L. Transplantation of the gracilis muscle for incontinence of urine. *J.A.M.A.* 82: 822, 1926.

51 Pickrell, K., Georgiade, N., Crawford, H., Maguire, C. and Boone, A. Gracilis muscle transplant for correction of urinary incontinence in male children. *Ann. Surg.* 143: 764, 1956.

52 Janknegt, R.A., Baeten, C.G.M.I., Weil, E.H.J., et al. Electrically stimulated gracilis sphincter for treatment of bladder sphincter incontinence. *Lancet* 340: 1129, 1992.

53 Williams, N.S., Fowler, C.G., George B.D., Blandly, J.P., Badenoch, D.F., and Patel, J. Electrically stimulated gracilis sphincter for bladder incontinence. *Lancet* 341: 115, 1993.

54 Janknegt, R.A., Heesakkers, J.P.F.A., Weil, E.H.J., and Baeten, C.G.M.I. Electrically stimulated gracilis sphincter (dynamic graciloplasty) for treatment of intrinsic sphincter deficiency: a pilot study on feasibility and side effects. *J. Urol.* 154: 1830, 1995.

55 Van Aalst, V.C., Werker, P.M.N., Stremel, R.W., Perez-Abadia, G.A., Petty, G.D., Heilman, S.J., Palacio, M.M., Kon, M., Tobin, G.R., and Barker, J.H. Electrically stimulated free-flap graciloplasty for urinary sphincter reconstruction: A new surgical procedure. *Plast. Reconstr. Surg.* 102: 84, 1998.

56 Palacio, M.M., Van Aalst, V.C., Perez-Abadia, G.A., Stremel, R.W. Werker, P.M.N., Ren, X., Petty, G.D., Heilman, S.J., Van Savage J.G., Garcia Fernandez, A., Kon M., Tobin, G.R., and Barker, J.H. Muscular urinary sphincter: Electrically stimulated myoplasty for functional sphincter reconstruction. *J. Urol.*, 160: 1867, 1998.

57 Cavina, E., Seccia, M., and Evangelista, G. Neo-sphincter and neo-stomy. New surgical views for myoelectric stimulated continence. A clinical experience. Preliminary report. Am. J. Proctol. Gastroenterol. *Colon Rectal Surg.* 33: 16, 1982.

58 Merrell, J.C., Russell, R.C., and Zook, E.G. Free microneurovascular gracilis muscle transfer in the dog for enterostomal sphincter construction and control: an experimental study. *Ann. Plast. Surg.* 17: 82, 1986.

59 Konsten, J., Baeten, C.G.M.I., van Mameren, H., Havenith, M.G., and Soeters, P.B. Feasibility of stoma continence, using electrically stimulated rectus abdominis muscle in pigs. *Dis. Colon Rectum* 36: 247, 1993.

Chapter 4

Functional Electrical Stimulation

Introduction

The reanimation of contractile function of muscle is an important advance in the field of reconstructive surgery. Contraction can be either done voluntarily after a few months when the muscle's nerve is coapted (e.g. dynamic reanimation in patients with facial paralysis[1]) or with the help of an external stimulator. The latter is needed when there is an upper motor neuron injury.[2] In this situation the paralyzed muscles have an intact lower motor neuron pathway from the spinal cord to the muscle endplate. To activate the paralyzed muscles an external electrical stimulus is needed. External stimulation is also required when a muscle is transposed and has to perform a function different from its native one even with intact nerve supply.[3]
The most optimal would be an electrical stimulation system that imitates the natural activation of skeletal muscle. The physiological route for activating skeletal muscle is via a complex mechanism in which the brain, spinal cord and peripheral nervous system are involved and interact.[4] The activity imposed by chronic electrical stimulation is simple but on the other hand can have adverse effects because of improper use. Therefore, by understanding the basic knowledge of physiologic and electrical muscle stimulation one can better understand and approach the problems encountered with electrical muscle stimulation.

Functional Electrical Stimulation (FES)

Functional electrical stimulation (FES) covers the general field of using electrical stimulation to recover a lost function. This applies to the central nervous system directly (e.g., cerebellar stimulation[5]), to cranial nerves (e.g., auditory prostheses[6]) and to the peripheral nervous system.[7] When applied in the last group to achieve functional movement, it is often referred to as functional neuromuscular stimulation (FNS). FNS is generally applied to stable neurological lesions where no further recovery is expected and it is accepted that the procedure should be effective for the lifetime of the user. Peripheral nerve stimulation also covers therapeutic stimulation, which is usually applied to enhance residual or temporarily diminished voluntary function and is of shorter duration. Finally peripheral nerve stimulation covers the field of dynamic myoplasty.

Peripheral Nerve Stimulation Physiology

Stimulation of excitable tissue is initiated by depolarizing the cell membrane. The resting transmembrane potential arises as a result of an ionic concentration difference in the intracellular and extracellular fluids of the cell body and axon. Normally, action potentials are generated by membrane potential changes following synaptic currents. Lowering this potential artificially results in the generation of a propagated action potential. Unmyelinated axons carry the action potential smoothly, while myelinated axons carry it in discrete steps but at faster speeds.

The threshold of stimulation is the minimum stimulus amplitude or duration needed to initiate an axon potential, and this translates to a minimum amount of cathodic charge transfer necessary. Peripheral nerve stimulation to gain muscle contraction depends on delivering a controllable amount of charge to the nerve through an extracellular electrode.[8] Action potentials can also be generated by anodic break currents. Since the thresholds for these are much higher, for practical FNS cathodic stimulation is universally used.

The amplitude of the pulse needed to start an action potential is greater for pulses of shorter duration. Though one would use long duration pulses to minimize the current amplitude needed, total charge transfer should be minimized to decrease the chance of tissue injury. The threshold charge also increases with pulse width increase. This increase is due to the fact that with long duration pulses, the charge is distributed rather than being concentrated at the excitation site.

In myelinated axons there is a constant relationship between the internodal distance and the diameter of the axon (internodal distance = 100 x diameter). Thus large-diameter axons have nodes further apart than small-diameter axons. As a result, under a uniform electrical field the large fibers have a larger potential difference between adjacent nodes. The result of this is that larger fibers have lower thresholds and fire before smaller fibers, which is the reversal of the physiologic recruitment order. Although this does not affect applications where the stimulation is delivered to the muscle through epimyseal or intramuscular routes, it does have importance in nerve cuff applications. Techniques have been developed using a special stimulation waveform to recruit small fibers before large.[9] In applications in which direct nerve cuff stimulation is used, the diameter of the axons in the nerve and their distances from the stimulating electrodes have an effect on the recruitment domain and order. There are strategies by which axons can be selectively activated. Thus, only large fibers or small fibers or a group of localized fibers can be stimulated.[10,11] During epimyseal and intramuscular stimulation the muscle is activated by direct nerve stimulation of the intramuscular muscle branches and not through muscle fiber stimulation. The thresholds for muscle fiber activation are much higher for direct muscle stimulation as compared to direct nerve stimulation.[12]

Electrophysiology

The use of metal electrodes for electrical stimulation necessitates the flow of ionic charge into tissues. This can occur by capacitative or faradic mechanisms. In the former there is alternate attraction and repulsion of ions but no net transfer of electrons. Thus there is no chance of chemical changes occurring. This is an ideal mechanism of charge injection, but is limited by the maximal amount of charge that can be transferred before the dielectric breaks down. Because the charge required for physiological stimulation far exceeds that available from capacitative mechanisms, FNS depends on faradic charge injection. Faradic mechanisms involve transfer of electrons, which means that some chemicals are oxidized or reduced. This can be reversible, as when an opposing current reverses the chemical changes of the preceding stimulation pulse and no new chemicals are formed or destroyed. Thus there is no corrosion of the electrode. In irreversible processes, material is lost into the extracellular fluid.

The guiding principle for selection of electrode materials and stimulation protocols is chemical reversibility. For a particular electrode material, there is a limit to the amount of charge that can be injected before reaching the limits of the reversible processes. This charge limit depends on the electrode material, its shape and size, and the stimulation waveform. The temporal pattern of the stimulus waveform is probably the most important criteria.[13] The least damaging waveforms are biphasic with no net direct current and charge densities within the reversible spectrum. The charges in each half of the waveform may be balanced with a symmetrical or asymmetric wave and there may be delays between the two parts of the biphasic pulse.

Biomaterials

Platinum and its alloys with iridium have been most widely used for electrical stimulation. Platinum is ideal for peripheral applications, while the addition of iridium oxide coatings allows smaller sized electrodes to be used.[13] Of the non-noble metals, 316L stainless steel has been widely used for intramuscular electrodes.

Leads are one of the critical parts of any stimulation system, either percutaneous or implanted, since they have to be able to withstand fatigue failure from shear and joint movement. The implanted stimulators are packaged in titanium with hermetic feedthroughs for the leads. With this type of packaging, the receiving coil has to be outside the main package to avoid significant loss of radiofrequency signal.[14] They also have been packaged in ceramic material, which allows all the components to be in one package, thus reducing the size of the stimulation device.

Adverse Effects

Potential adverse effects of peripheral neuromuscular stimulation are the possibility of tissue damage, unwanted spillover patterns and pain. The mechanism of tissue damage falls into two categories: first, from toxicity from products of electrode dissolution, and second, from non-electrochemical mechanisms like vascular damage or neural membrane damage from passage of the electrical current.[15] The electrochemical problem can be migated by following safe stimulation techniques as previously discussed. Long-term stimulation of muscles using intramuscular or epimyseal electrodes can be done with no deleterious effects. Nerve cuff electrodes have the potential for causing greater damage, but careful regulation of the stimulation parameters, charge densities, total charge delivered, and electrode configurations can minimize this.

Nerve cuff electrodes have been used for many applications ranging from phrenic nerve stimulation for respiratory assist to dynamic cardiomyoplasty. As various the applications are as diverse the long-term effects are, even within the application. Glenn *et al*. reported a study in which quadriplegic patients with respiratory paralysis have been treated by electrical stimulation of the phrenic nerves to pace the diaphragm.[16] The average time the 13 patients have had bilateral diaphragm pacemakers is 26 months. Injury to the phrenic nerves either by initial trauma to the cervical cord or during operation for implantation of the nerve cuff was the most significant complication. In spite of this, nerve damage from prolonged electrical stimulation has not been a problem in this study.

Application Basics

Stimulation parameters selected for electrical stimulation have the objective of depolarizing the specific fibers in the peripheral nerve generally to effect movement of a particular muscle group or groups without evoking an undesirable sensation. Because recruitment is affected by the number of active motor units and the rate of their firing, the stimulation parameters must allow these two variables (i.e., recruitment and temporal summation).

There are different anatomic routes and sites for the placement of electrodes, and this diversity affects the efficacy, selectivity, adverse effects, and the stimulation parameters needed. Three types of electrodes are used, classified by invasiveness as surface, percutaneous, and implanted. With each of these electrodes, stimulation can be monopolar or bipolar. The stimulus waveform used to affect excitation is generally a biphasic current controlled waveform with equal charge contained under the negative and positive going components of the stimulus and waveform. The current controlled phase (in contrast to using a voltage controlled phase) insures delivery of the desired amount of current to the nerve regardless of tissue impedance changes that might occur at the electrode with encapsulation.

Control of activation of the number of motor units is obtained by increasing either the current or the pulsewidth of the stimulation. Recruitment obtained in this way activates more and more motor units as either the stimulus amplitude or pulse width is increased. However, recruitment is a nonlinear property and the force versus stimulus characteristics generally show no force generated up to a specific stimulation level (known as threshold), followed by a nonlinear in the magnitude of force with increasing magnitude of stimulation. The specific relationship between the stimulus input and the force developed is unpredictable and depends significantly on the geometric relationship of the electrode to the desired nerve fibers. Thus this must be determined experimentally.

In a case of muscle-based electrodes, muscular contraction is elicited through activation of the peripheral nerve, but the electrode generally is not immediately adjacent to the nerve itself, but is rather based on or in the muscle. These electrode types generally are thus less efficient in affecting neural activation and may require a stimulus as high as 20 mA and a stimulus pulse width of as high as 200 μsec to affect strong activation of the muscle.

Muscle Fatigue

General

A universal complication of all functional electrical stimulated muscle in situ or transferred muscle (dynamic myoplasty) is muscle fatigue. Muscles require maintenance of adenosine triphosphate (ATP) within the myofibers to generate force through the contractile interaction of actin and myosin proteins. In the absence of adequate oxygen delivery, muscle dependence upon aerobic mechanisms of metabolism for ATP generation will become limited and dependence upon anaerobic metabolic mechanisms will prevail. A consequence of this shift to anaerobic metabolism is a reduction in ATP production and an increase in lactic acid production. While the etiology of muscle fatigue is complex and can result from many contributing factors, the combination of decreased ATP availability and decreased intracellular pH from lactic acidosis certainly contribute to the failure of muscle to produce contractile force.[17]

In activation of muscle, electrical stimulation provides an unnatural means of eliciting firing of the motor units. All other factors considered equal, the recruitment order achieved for electrical stimulation is through large motor units (innervating fast-contracting, fast-fatiguing motor units) being excited at lower thresholds than those for slow contracting, slow twitch motor units.

This is the reverse order of recruitment of that achieved during normal voluntary contraction.[18,19] In actual implementation the activation pattern is considerably more complex because smaller motor units may be closer to the electrode than larger motor units. Thus, the inverse size principle may not be as critical in differentiating the recruitment order. These alterations of the metabolic properties of the muscle are important in its ultimate clinical use. In particular one encounters reductions in either the maximum force that can be generated or the ability to sustain muscle contraction.

With regard to fatigue, two properties are known to be most important. They are the metabolic profile of the muscle which is being excited and the frequency of stimulation which is delivered to the nerve. For the metabolic profile it is well known that most muscles are composed of motor units that possess different contractile properties, which allow them to act over a wide range of speed of contraction and endurance. In upper motor neuron injury paralyzed muscle is distinguished by having lost many characteristics and is composed of a greater uniformity of fibers, which contractile speeds are similar to fast contracting and relaxing and fast fatiguing.[20] Because of this, electrically stimulated muscle fatigues quite rapidly and generates little force.

A second factor with a significant influence on muscle fatigue is the frequency of activation. It is well known that the muscle generates greater force at higher stimulus frequencies and that a minimum stimulus frequency of 10 to 15 Hz is required to produce a fused contraction of a muscle with slow contraction characteristics. Stimulation at low frequencies is desired, because the force-time properties of the muscle are extended. Thus, in obtaining functional use of muscle, one desires low frequencies for greater endurance but higher frequencies for increased force.

Fatigue in FES

Various methods have been used to reduce fatigue in functional electrical stimulation. These include 1. Chronic electrical stimulation in an attempt to convert fast type II fatigue prone fibers to slow type I fatigue resistant fibers; 2. Modulation of electrical parameters; 3. Alternate stimulation, whereby the different muscles that do the same function are stimulated alternately (e.g. stimulating different muscles in the lower limb alternately to maintain tedious tasks as standing); 4. Sequential stimulation and 5. Varying regimens of nerve stimulation. Each of these methods has its advantages and disadvantages.

In dynamic myoplasty typically muscles are moved to new locations while maintaining only one neurovascular pedicle and then forced through extraneous pulse generators to functionally perform in this new location. The new functional demand is not normal for this muscle and thus fatigues fairly easily. In dynamic myoplasty muscle fatigues primarily for two reasons: they have inadequate perfusion and or they are stimulated to contract at a frequency that is incompatible with their basic muscle fiber type (the latter being in all functional electrical stimulation applications). The use of extraneous stimulation devices produces skeletal muscle contractions capable of generating significant force but the muscle cannot maintain force generation due to fatigue of the muscle. As an anatomical muscle contracts, the individual myofibers within the muscle place significant pressure on the blood vessels within the muscle. Due to these high transmural pressures, a tetanic contraction has the effect of occluding blood flow through the muscle during contraction. This reduction of perfusion due to internal muscle pressure contributes to the failure to deliver adequate oxygen and nutrients to the contracting muscle and precipitates fatigue of the muscle and failure to generate force despite continued stimulation.

Another factor in dynamic myoplasty that indirectly contributes to fatigue might be the unfavorable resting length from which the muscle has to start contracting. It is known that the length of the muscle in terms of bridge kinetics has a determining influence on the force it can generate.[21] In a sphincter model the muscle is wrapped in the shape of a cylinder. Since the muscle is not fixed any more via its tendons it shortens because of its elastic components. In the shortened position maximum contractile strength cannot be developed since there is not an optimum overlap of actin and myosin filaments.

Training Regimen

An approach used in dynamic myoplasty to avoid muscle failure due to fatigue is to train the muscle to enhance fatigue resistance.[22-24] Training protocols currently in use require an 8 week period of stimulation at increasing frequency until the muscle is converted to a fatigue resistant fiber type. Skeletal or striated muscles are normally a mixture of fatigue-prone, fast-twitch, glycolytic (type II) and fatigue-resistant, slow-twitch, oxidative (type I) muscle fibers. The innervation and the function of the muscle determine the predominance of one fiber type over another and all fiber types in a given motor unit are the same. But striated muscle is plastic in nature and the training regimen transforms the muscle to predominantly type I. The trade-off for producing fatigue resistance is a slower contracting muscle capable of generating less power than its innate character.[25]

Sequential Stimulation

While there are many factors that probably contribute to the found difficulties in using a training protocol to enhance fatigue resistance, one reason for the variable outcomes could relate to the way the muscle is being electrically stimulated. Under normal circumstances, a given anatomical muscle can respond and adapt to generation of fine control, prolonged sustained activity, or brief intense activity. The response generated by muscle depends upon the types of motor units (and therefore myofiber types) contained within the muscle and the pattern of activity in which they are engaged.[26] Current applications of dynamic myoplasty call for tetanic stimulation and contraction of all myofibers simultaneously. This tetanic type contraction occurs rarely in normal conditions and can lead to irreversible muscle damage.

On the basis of the earlier described drawbacks of training regimens an entirely different -more physiologic- approach to minimize skeletal muscle fatigue was developed by Zonnevijlle *et al*. Rather than stimulating an entire gracilis muscle in one electrical burst and thus recruiting the same fibers simultaneously, they studied the feasibility of stimulating different gracilis muscle segments sequentially. This approach allows parts of the muscle to rest while other parts work. This sequential segmental neuromuscular stimulation (SSNS) of the gracilis significantly enhanced resistance to fatigue in comparison with whole muscle stimulation.[27] These findings agreed with literature addressing endurance enhancement in neuromuscular prosthesis research for gait, in which alternation between agonistic muscles proved to be beneficial.[28,29] They are also in agreement with observations described in the literature concerning the indirect or neural multichannel stimulation, which was also developed to sequentially recruit separate parts of a muscle.[30-32]

Feedback Control

The control paradigms used in FNS have been described as open-loop and closed-loop systems. In the open-loop paradigm, a single command or group of commands is used to supply a stimulus to the muscle, which then for example generates a force acting across the joint. The resulting torque is balanced by the load, gravity, or an opposing muscle. In the open-loop system, a single command is used to simultaneously control the stimulus levels, which are provided to an entire group of muscles that generate a coordinated action. This system does not incorporate any changes in the performance of the muscle, such as fatigue or changes in the load, in the predicted performance. Rather, the subject has the entire responsibility of using the command to regulate the output performance. In contrast, closed-loop control uses sensors to alter the performance of the system.[33] An example of a closed-loop system would be one in which detection of muscle force is required because of fatigue. In this case, by measuring muscle force, the control system can automatically compensate for changes in the muscle force due to an alteration in muscle performance. There are many other examples of such closed-loop control systems, including walking systems, in which the contact of the foot on the floor is used to regulate subsequent stimulus actions, and control systems, in which a sensor is provided to the joint to ensure that the joint moves through its desired trajectory at a known rate.[34] Closed-loop systems clearly require sensors as a critical element in their implementation. Significant effort has gone into developing sensors for measuring parameters such as foot to floor contact, force grasp, individual muscle force through the bioelectric signal, intramuscular bioelectrical signal, intramuscular pressure and tendon force, joint angle and so forth.[35] Complex arm movements, involving grasp and release control of the forearm, wrist, elbow, and shoulder, have been achieved by using feedback control.[36]

SSNS was introduced by Zonnevijlle *et al*. to reduce muscle fatigue in applications like graciloplasty, so that a prolonged training period could be avoided and the neo-sphincter could be activated soon after surgery to improve patient quality of life more immediately than current approaches permit.[27] To produce this most desired effect, the muscle was proposed to animate in a fashion that allowed it to contract according to need. A normally functioning native sphincter utilizes control mechanisms to regulate when and to what degree contraction occurs, thus maintaining continence without resorting to maximal sphincter contraction for prolonged periods of time. Therefore, closed-loop control of the force generated by the neo-sphincter was applied and combined with SSNS to mimic true physiologic sphincter function.[37] This study showed that closed loop control and sequential segmental stimulation can be effectively combined to acutely control force generation.

References

1 Siebert, J.W., Anson, G., and Longaker, M.T. Microsurgical correction of facial asymmetry in 60 consecutive cases. *Plast. Reconstr. Surg.* 97: 354, 1996.

2 Bhadra, N., and Peckham, P.H. Peripheral nerve stimulation for restoration of motor function. *J. Clin. Neurophysiol.* 14: 378, 1997.

3 Grandjean, P., Acker, M., Madoff, R., Williams, N.S., Woloszko, J., and Kantor, C. Dynamic myoplasty: Surgical transfer and stimulation of skeletal muscle for functional substitution or enhancement. *J. Rehabil. Res. Dev.* 33: 133, 1996.

4 Salmons, S. Exercise, stimulation and type transformation of skeletal muscle. *Int. J. Sports Med.* 15: 136, 1994.

5 Davis, R., Barolat-Romana, G., and Engle, H. Chronic cerebellar stimulation for cerebral palsy. Five-year study. *Acta. Neurochir. Suppl. (Wien)* 30: 317, 1980.

6 Clark, G.M., Tong, Y.C. and Patrick, J.F. *Cochlear prosthesis.* New York: Curchill-Livingstone, 1990.

7 Hambrecht, F.T. Neural prostheses *Annu. Rev. Biophys. Bioeng.* 8: 239, 1979.

8 Peckham P.H. Functional electrical stimulation. In: Webster J., editor. *Encyclopedia of medical devices and instrumentation*, vol. 2. New York: John Wiley & Sons. 1988: 1331-1352.

9 Fang, Z.P., and Mortimer, J.H. Selective activation of small motor axons by quasitrapezoidal pulses. *IEEE Trans. Biomed. Eng.* 38: 168, 1991.

10 Veraart, C., Grill, W.M., and Mortimer, J.T. Selective control of muscle activation with a multipolar nerve cuff electrode. *IEEE Trans. Biomed. Eng.* 40: 640, 1993.

11 Grill W.M., and Mortimer J.T. Stimulus waveforms for selective neural stimulation. *IEEE Eng. Med. Biol.* 14: 375, 1995.

12 Crago, P.E., Peckham, P.H., Mortimer, J.T., and Van der Meulen, J.P. The choice of pulse duration for chronic electrical stimulation via surface, nerve and intramuscular electrodes. *Ann. Biomed. Eng.* 2: 252, 1974.

13 Robblee L.S., and Rose T.L. Electrochemical guidelines for selection of protocols and electrode materials for neural stimulation. In: Agnew W.F., McCreery D.B., eds. *Neural prostheses; fundamental studies.* New Jersey: Prentice Hall. 1990: 26-66.

14 Peckam P.H. and Smith B. Implanted stimulators for neuromuscular control. In: Brozino, J.D, ed. *The biomedical engineering handbook.* Boca Raton, FL: CRC Press, 1995: 1270-1274.

15 Agnew W.F., McCreery D.B., Yuen T.G.H., and Bullara L.A. Histologic and physiologic evaluation of electrically stimulated peripheral nerve: considerations for the selection of parameters. *Ann. Biomed. Eng.* 17: 39, 1989.

16 Glenn W.W., Holcomb W.G., Shaw R.K., Hogan J.F. and Holschuh K.R. Long-term ventilatory support by diaphragm pacing in quadriplegia. *Ann. Surg.* 183: 566, 1976.

17 Fitts, R.H. Cellular, molecular, and metabolic basis of muscle fatigue. 1996. In: Rowell L.B., Sheperd J.T., eds. *Handbook of Physiology*, Section 12, Exercise: Regulation and Integration of Multiple Systems. New York: Oxford University Press. p1151-1183.

18 McMiken D.F., Todd-Smith M. and Thompson C. Strengthening of human quadriceps muscles by cutaneous electrical stimulation. *Scand. J. Rehabil. Med*. 15: 25, 1983.

19 Salmons S. The adaptive capacity of skeletal muscle and its relevance to some therapeutic uses of electrical stimulation. Proc. Int. Symp. Cell Biology and Clinical Management. In *Functional electrostimulation of neurons and muscles*. Italy: Abamo Terme, 1985: 71.

20 Peckham P.H., Mortimer J.T. and Marsolais E.B. Alteration in the force and fatigability of skeletal muscle in quadriplegic humans following exercise induced by chronic electrical stimulation. *Clin. Orthop. Rel. Res*. 114: 326, 1976.

21 Tabary, J.C., Tabary, C., Tardieu, C., Tardieu, G., and Goldspink, G. Physiological and structural changes in the cat's soleus muscle due to immobilization at different lengths by plaster casts. *J. Physiol.* 224: 231, 1972.

22 Williams, N.S., Hallan, R., Kroeze, T.H., and Watkins, E.S. Construction of a neorectum and neoanal sphincter following previous proctocolectomy. *Br. J. Surg*. 76: 1191, 1989.

23 Baeten, C.G.M.I., Geerdes, B.P., Adang, E.M., et al. Anal dynamic graciloplasty treatment of intractable fecal incontinence. *N. Engl. J. Med*. 332: 1600, 1995.

24 Mavrantonis, C., and Wexner S.D. Stimulated graciloplasty for treatment of intractable fecal incontinence. *Dis. Colon Rectum* 42: 497, 1999.

25 Pette, D., and Vrbova, G. Adaptation of mammalian skeletal muscle fibers to chronic electrical stimulation. *Rev. Physiol. Biochem. Pharmacol*. 120: 115, 1992.

26 Saltin, B., and Gollnick, P.D. Skeletal muscle adaptability: significance for metabolism and performance. 1983. In: Peachey L.D, ed. *Handbook of Physiology*, Section 10, Skeletal Muscle. Maryland: Williams & Wilkins Co. p555-631.

27 Zonnevijle E.D.H., Somia N.N., Stremel R.W., Maldonado C.J., Werker P.M.N., Kon M., and Barker J.H. Sequential segmental neuromuscular stimulation: an effective approach to enhance fatigue resistance. *Plast. Reconstr. Surg*. 105: 667, 2000.

28 Peckham, P.H., Van der Meulen, J.P., and Reswick, J.B. Electrical activation of skeletal muscle by sequential stimulation. In Wulfson and A. Snaces (Eds), *The nervous system and electrical currents*. New York: Plenum, 1970.

29 Pournezam, M., Andrews, B.J., Baxendale, R.H., Phillips, G.F., and Paul, J.P. Reduction of muscle fatigue in man by cyclical stimulation. *J. Biomed. Eng*. 10: 196, 1988.

30 Petrofsky, J.S. Sequential motor unit stimulation through peripheral motor nerves in the cat. *Med. Biol. Eng. Comput*. 17: 87, 1979.

31 Baer, G.A., Talonen P.P., Shneerson J.M., Exner G., Markkula H., and Wells, F.C. Phrenic nerve stimulation for central ventilatory failure with bipolar and four-pole electrodes systems. *Pacing Clin. Electrophysiol.* 13: 1061, 1990.

32 Thoma, H., Frey, M., Girsch, W., et al. First experimental application of multichannel stimulation devices for cardiomyoplasty. *J. Card. Surg*. 6 (1 Suppl): 252, 1991.

33 Crago, P.E., Mortimer, J.T., and Peckham, P.H. Closed-loop control of force during electrical stimulation of muscle. *IEEE Trans. Biomed. Eng*. 27: 306, 1980.

34 Jaeger R.J. Design and stimulation of closed-loop electrical orthoses for restoration of quiet standing in paraplegia. *J. Biomech.* 19: 825, 1986.

35 Crago, P.E., Chizeck H.J., Neuman, M.R., and Hambrecht, F.T. Sensors for functional neuromuscular stimulation. *IEEE Trans. Biomed. Eng.* 33: 256, 1986.

36 Bhadra, N. and Peckham P.H. Peripheral nerve stimulation for restoration of motor function. *J. Clin. Neurophysiol.* 14: 378, 1997.

37 Zonnevijlle, E.D.H., Somia, N.N. Perez-Abadia, et al. Three parameters optimizing closed loop control in sequential segmental neuromuscular stimulation. *Artif. Organs* 23: 388, 1999.

Chapter 5

Use of the Rectus Abdominis Muscle for Abdominal Stoma Sphincter Construction: An Anatomical Feasibility Study

Janou W.J.M. Bardoel, M.D.
Wayne K. Stadelmann, M.D.
Gordon R. Tobin, M.D.
Paul M.N. Werker, M.D., Ph.D.
Richard W. Stremel, Ph.D.
Moshe Kon, M.D., Ph.D.
John H. Barker, M.D., Ph.D.

Plast. Reconstr. Surg. 105: 589, 2000.

Introduction

In the few studies that have been done to investigate the feasibility of using dynamic myoplasty to provide stomal continence *denervation atrophy* was one of the two main problems that lead to failure.[1-3] To approach this problem of denervation atrophy we conducted an anatomic study to design a muscle flap sphincter that would preserve as much innervation as possible and be anatomically situated for stoma formation. The most likely would be a muscle flap that would not need a neuro-vascular micro-anastamosis.

Muscle Selection

Following initial anatomical pilot studies we selected the rectus abdominis muscle (RAM) as the ideal muscle for creation of a stomal sphincter. The rectus abdominis muscle has been extensively used in reconstruction of breast,[4] thorax,[5] vagina,[6,7] bladder[8,9] and extremity defects.[10,11] For these purposes the RAM was used to replace or cover a defect. In far less of an extent the RAM has been used for replacing lost contractile function. A part of the RAM, after neuro-vascular micro-anastamosis, has been used for dynamic reanimation in patients with facial paralysis.[12,13] The RAM has also been used as a skeletal muscle ventricle in the dog heart.[14]

The RAM appeared to be the most promising myoplasty muscle for stomal sphincter construction for the following reasons: 1. The RAM is ideally located in close proximity to the lower abdominal quadrants where fecal stomas are most often brought out through the abdominal wall. Therefore the RAM could be transferred without the need for neuro-vascular micro-anastamosis. 2. It is a long, broad muscle that can provide adequate muscle length for a circumferential wrap around a stoma. 3. It has an axial blood supply from the deep inferior epigastric artery and veins that is very reliable and consistent.[15-17] 4. Dissection can be performed through the same laparotomy incision used to expose the bowel. 5. It has minimal donor-site morbidity.

Donor-site Morbidity

The rectus abdominis muscle is one of the muscles concerned in regulating the so-called intra-abdominal pressure and in acting, together with others, as a muscle of expiration. It flexes the lumbar spine, increases intra-abdominal pressure, pushes the diaphragm upwards in forced expiration, and acts in sneezing, lifting heavy objects and during parturition and vomiting. Great exertion is demanded on the muscle when the body is raised from the horizontal to the sitting posture without the aid of the arms, and also by violent coughing and the strain of defecation.

Most of the published studies concerning the donor-site morbidity of using the rectus abdominis muscle have been after pedicled or free TRAM-flap surgery for breast reconstruction.[18,19] Kroll *et al*. reviewed the incidence of postoperative abdominal bulge, hernia, and the ability to do sit-ups in a series of 268 patients who had undergone free (unilateral and double-pedicle bilateral) TRAM or conventional (single-pedicle and double-pedicle or bilateral) TRAM flap breast reconstruction.[19] The incidence of abdominal bulges (3.8%) and hernia (2.6%) was similar in the four groups. However, the ability to perform sit-ups was greatest in the unilateral free TRAM group (63%) and lowest in the double-pedicle or bilateral conventional TRAM group (27%). At the same time there are reports about incidences of serious weakness and hernias of the abdominal wall in patients undergoing TRAM-flap breast reconstruction of up to 35%.[20] To reduce donor site morbidity, more attention has been given recently to limiting the amount of muscle resection. This has led to the development of the deep inferior epigastric perforator (DIEP) flap.[21] These perforator flaps reduce donor site morbidity to the lowest level yet possible.[22]
Free transfer of the segmental rectus abdominis muscle flap is one of the standard procedures for free flap coverage of medium-size defects.[11] Geishauser and co-workers evaluated the donor-site morbidity of the segmental rectus abdominis muscle flap for lower extremity defects in 20 patients with an average follow-up time of 47-months. In the cases included in this investigation only the caudal segment of one rectus muscle and les than one-third of the total length of the rectus abdominis muscle had been harvested.[23] In only 1 patient they found one small hernia in the region of the scar. Grading of the muscle strength of the anterior abdominal wall using the test described by Janda (three exercises, Grades 0-5) was 5 in fourteen patients (70%) and 4 in five patients (25%).
The amount of rectus abdominis muscle we need for stomal sphincter construction is in between one-third and half of the total length of the rectus. In contrary to Geishauer *et al*. we need to make an opening in the anterior and posterior rectus fascia to let the stoma pass through.

Flap Design Rectus Abdominis Muscle: Anatomical Feasibility

The RAM has been used for a variety of different reconstructive procedures and its anatomy has been well documented. In spite of this, a detailed anatomical description of the RAM's nerve and blood supplies relative to it's being used to create a fecal stomal sphincter has not been published.[24-28] The purpose of the following experiment was to describe the anatomy of the RAM in the context of creating an innervated and pedicled fecal stoma neo-sphincter. To determine the anatomical feasibility of creating a flap that, in future studies, could be electrically stimulated, we performed detailed dissections in fresh human cadavers. The objectives addressed include the following: (1) definition of the innervation pattern of the entire rectus abdominis muscle; and (2) determination of the ideal rectus abdominis muscle flap configuration for constructing a stoma sphincter and preserving as much of its native innervation and vascular supply as possible.

Materials & Methods

A total of 24 RAMs in 14 fresh human cadavers (9 male, 5 female) were investigated. Of the 14 cadavers, 10 underwent bilateral dissections. In the remaining four cadavers only one RAM could be dissected due to the presence of surgical scars on the contralateral side.

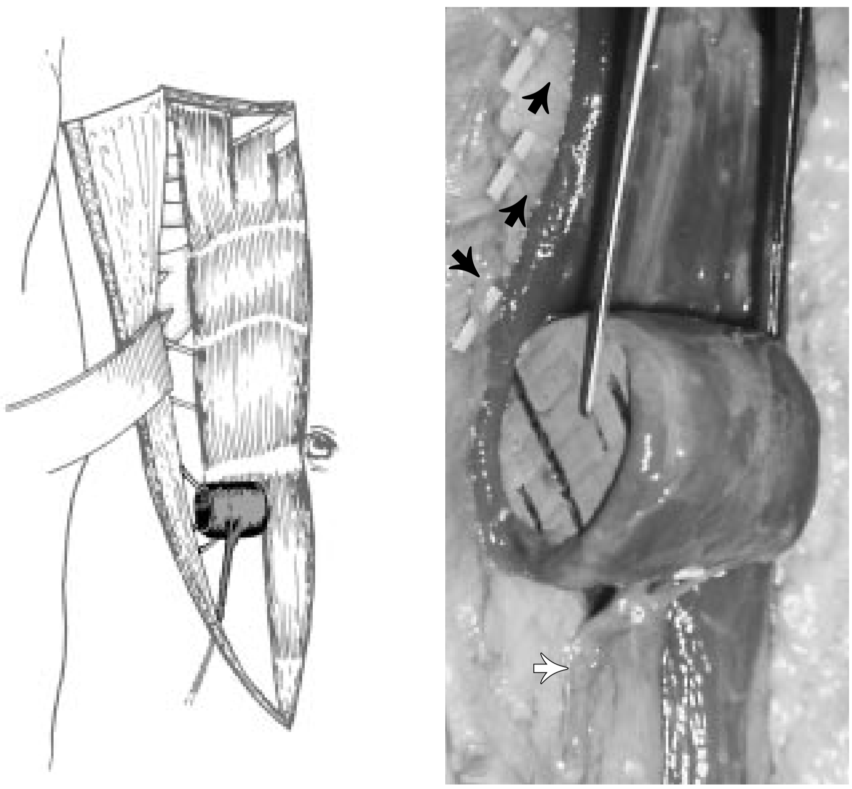
The first part of the investigation consisted of defining the neurovascular anatomy of the RAM. The following measurements were carried out in each mobilized RAM: 1. the vertical and horizontal distance of the point of entrance of all the intercostal nerves innervating the RAM along its posterior surface using the caudal insertion and the lateral muscle margin as reference points. 2. the number of intercostal nerves innervating the most caudal segment of the muscle (between the symphysis pubis and the most caudal tendinous intersection). 3. the vertical and horizontal distance of the point of entrance of the vascular pedicle using the caudal insertion and the lateral muscle margin as reference points.

The second part of the investigation consisted of defining the best possible RAM flap sphincter design that would both preserve the muscles' nerve and blood supply.

A mid-line laparotomy from the xiphoid process to the pubic symphysis was used to expose one or both RAMs. The anterior rectus fascia was incised along the medial border of the muscle and was reflected laterally to the lateral margin of the RAM. Marking sutures were placed at the tendinous distal insertion and tendinous intersections to insure that the muscle was returned to its original length after detaching it from its distal insertion. The inferior insertion of the RAM was transected from its bony insertion on the pubic symphysis. The deep inferior epigastric vascular pedicle consisting of an artery (DIEA) and two veins was dissected back to its take off at the external iliac artery. Muscle mobilization was carried out by individually dissecting each intercostal neurovascular bundle laterally with the assistance of an operating microscope (Zeiss, Gera, Germany). The most caudal segment of the RAM was divided longitudinally in the para-sagittal plane. The lateral segment was wrapped around a 3-cm diameter stent that simulated a fecal stoma.

The following two sphincter configurations were compared: a peninsula flap (n = 24) and an island flap (n = 16). With the superiorly based peninsula flap design, the detached caudal portion of the rectus muscle was rolled circumferentially around the stoma stent with the ventral surface of the muscle coming to lie against the stent (Fig. 1). The cranial portion of the muscle was not divided from the caudal segment that was wrapped around the stoma. The long axis of the stoma sphincter was parallel to the abdominal wall. The following measurements were undertaken: 1. the length of the most caudal segment of the rectus muscle with and without the tendinous insertion; 2. the RAM thickness of the caudal segment at its midpoint; and 3. the degree of muscle overlap around the stent after the wrap.

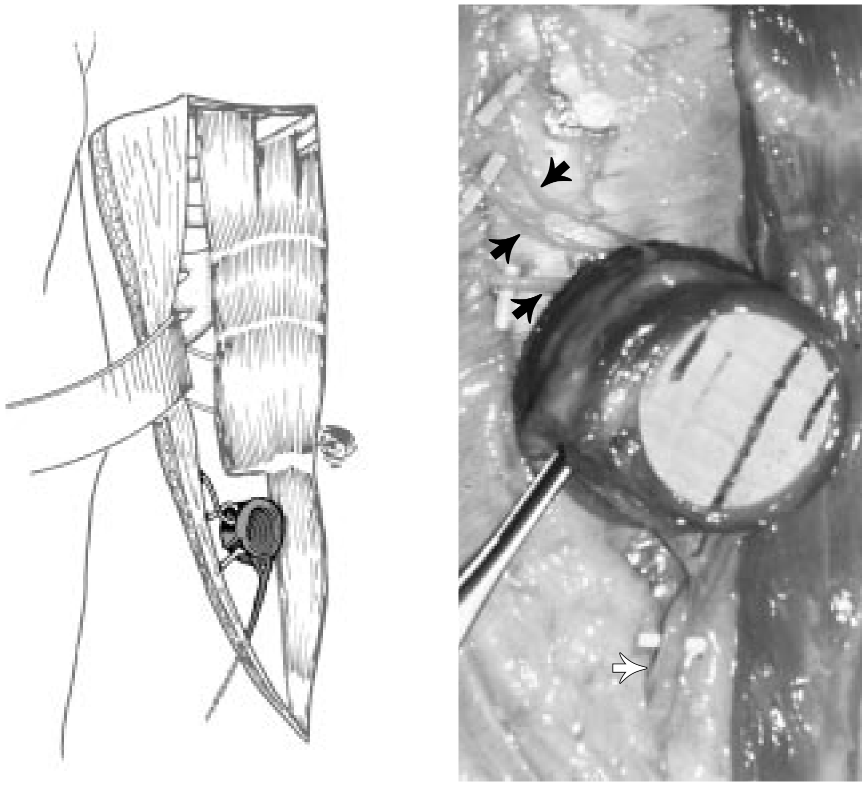
Figure 1
Rectus abdominis muscle, peninsula flap stoma sphincter design in human cadavers. (*Left*) Line drawing representation. (*Right*) Cadaver dissection. The detached caudal portion of the rectus abdominis muscle is wrapped circumferentially around a stoma stent, with the ventral surface of the muscle coming to lie against the stent. The *solid arrows* indicate the segmental intercostal nerves. The *open arrow* indicates the vascular pedicle.



The second sphincter configuration was the island flap (n = 16). The island flaps were constructed by modifying the last consecutive 16 peninsula flaps. This configuration is the same as the peninsula flap with the major difference that the RAM is transected at the caudal most intersection. The distal muscle segment was then rotated 90^0 laterally to allow the stoma sphincter to stand perpendicular to the abdominal wall (Fig. 2). The following measurements were taken for this sphincter design: 1. the amount of muscle overlap after it

Figure 2

Rectus abdominis muscle, island flap stoma sphincter design in human cadavers. (*Left*) Line drawing representation. (*Right*) Cadaver dissection. The rectus abdominis muscle is transected at the most caudal intersection, followed by 90-degree, lateral rotation of the distal muscle segment that allows the created stoma sphincter to stand upright. The *solid arrows* indicate the segmental intercostal nerves. The *open arrow* indicates the vascular pedicle.



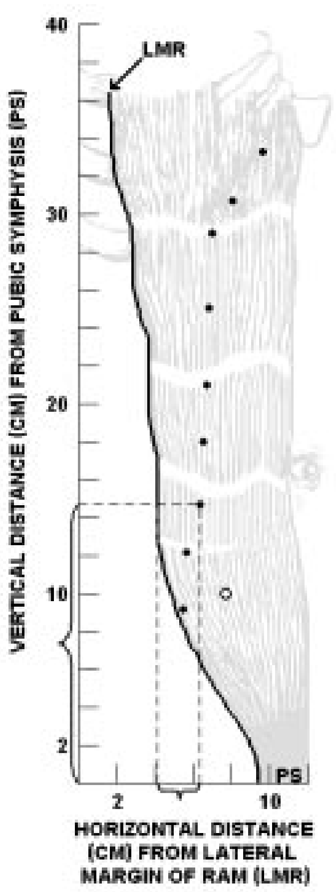
was wrapped around the stent; 2. the degree of nerve mobilization proximal to the rectus fascia needed to allow for tension-free stoma sphincter construction; and 3. the amount of sphincter projection above the abdominal wall.

Results

The location at which the intercostal nerves enter the RAM along its posterior surface is shown in Figure 3. The number of intercostal nerves innervating the caudal segment was two in 13%, three in 54% and four in 33% of the RAM dissections. The Deep Inferior Epigastric Pedicle was 10.0 ± 0.5 cm (*VD*) from the pubic symphysis and 2.7 ± 0.2 cm (*HD*) from the lateral margin of the RAM (Fig. 3).
The average length of the caudal rectus segment was 13.3 cm (10.5 to 18.5 cm) without the tendinous insertion of the muscle and 15.5 cm (12.5 to 20.5 cm) with the tendinous portion included. On average, the distal tendinous portion of the muscle was 2.7 cm long (1.5 to 3.5cm). The RAM thickness of the caudal segment at its midpoint was 5.7 ± 0.5 mm (range 3.0 to 12.0 mm).
The amount of muscle overlap around the three-centimeter stent varied with the type of flap being used. Using the peninsula flap the overlap was 0.5 cm (-2.0 to 2.9 cm). In two of the 24 peninsula flap sphincters there was no muscle overlap. In all the island flap sphincters there was complete muscle overlap the extent of which depended on the length of the caudal segment. The average amount of overlap for the island flap was 4.8 cm (1.0 to 9.0 cm).
In all peninsula flap sphincters, the amount of mobilization achieved by dissecting the intercostal nerves up to the lateral border of the rectus muscle was sufficient to allow the wrap to occur without tension on the nerves. No further nerve mobilization was needed. In the island flap design, nine of the 16 flaps (56%) could not be wrapped around the stent unless one or more of the intercostal nerves were dissected from the fascial plane between the internal oblique and the transversus abdominis muscles. One nerve in seven flaps and two nerves in two flaps had to be dissected anywhere from one to three centimeters in order to permit the wrap to occur without placing undue tension on either the nerves or the vascular pedicle.
The sphincter projection as determined by the width of the island flaps, was 4.0 ± 0.2 cm (range 3.0 to 7.0 cm). In only one dissection was it necessary to use almost the entire width of the muscle due to a very medially located insertion of the vascular pedicle.

Figure 3

Location of the entrance of the intercostal nerves (*solid dots*) and the deep inferior epigastric pedicle (*open dot*) into the rectus abdominis muscle along its posterior surface. The vertical distance (*VD*) of the point of entrance uses the caudal insertion at the pubic symphysis (*PS*) as a reference point (*y-axis*). The horizontal distance (*HD*) of the point of entrance uses the lateral margin of the rectus abdominis muscle (*LMR*) as a reference point (*black solid line*). As an example, the brackets indicate the actual distance (in centimeters) at which the third intercostal nerve enters the muscle.



Discussion

Fecal stomal incontinence continues to pose a major problem for patients who suffer with them, for health care professionals responsible for caring for these patients and for the health care system responsible for their costs. Previous attempts to create a continent stoma using dynamic myoplasty procedures have met with less than ideal outcomes. Failures were reported to have been due primarily to denervation atrophy and muscle fatigue of the newly created sphincter. In an attempt to solve the problem of muscle denervation we performed the present anatomical studies. We designed a muscle flap that required minimal muscle denervation in its creation.

Ideally, a muscle chosen for stoma sphincter construction should be situated in close proximity to the proposed stoma location so that local muscle flaps could be used to create the sphincter. In addition, a muscle flap designed for stoma sphincter construction should preserve as much innervation as possible so that sphincter function is not compromised. After carefully considering various muscles for creating a stoma sphincter we chose the rectus abdominis muscle since it appeared to be the best suited choice for this application.

In a thorough literature search we could not find anatomical descriptions of the RAM's innervation that pertained to our specific application i.e. creation of a stoma sphincter. Previous anatomical studies that described the innervation pattern of the RAM did not include exact data pertaining to the number of nerves entering the RAM and at what distance from the pubic symphysis they entered. According to Duchateau *et al.*[29] six to eight intercostal nerves were found to pass into the RAM along a line extending from the costal margin and xiphoid process down to the pubic symphysis. Below the umbilicus, two to three nerves were reported to enter the segment of muscle below the arcuate line. These nerves were noted to become intramuscular shortly after passing beneath the lateral margin of the muscle. Information concerning the vertical distribution of the intercostal nerves entering the RAM, however, was not presented. Similar findings were presented by Bishop *et al.*[26], Rouvière *et al.*[27] and Testut *et al.*[28] According to Cullen *et al.*[25] at the lateral margin of the rectus sheath, there are 5 to 8 fascial perforations through which the intercostal nerves and vessels enter at fairly regular intervals. However, the location of the end distribution was noted to be highly variable. Other published anatomical studies did not provide us with the specific data needed for our application.[30,31]

Our anatomical dissections revealed that the RAM is in the appropriate anatomic location for a stoma; indeed many current methods of stoma creation include delivering the intestine directly through this muscle. The RAM is a long, broad muscle that can easily be circumferentially wrapped around a stoma when lifted as a flap. The muscle has a robust vascular supply from the dominant deep inferior epigastric artery and veins,[15,16] and as our dissections demonstrated, its nerve supply can be kept intact without limiting its arch of rotation. There were, however, some limitations encountered in positioning the sphincter on the abdominal wall. The length of the DIEA pedicle supplying the RAM sphincter limited the distance that the stoma could be positioned cephalad to the pubic symphysis. Conversely, the factor determining the cephalad position of the sphincter depends on the flap design used. With the island flap, the most cranial intercostal nerve(s) limited the mobility of the sphincter. In 9 of 16 island flaps a more extensive mobilization of the intercostal nerves was needed to provide enough mobility to complete the wrap. In case of the peninsula flap the muscle itself limited the mobility of the sphincter. The fact that the peninsula flap design consisted of not dividing the muscle above the most caudal tendinous intersection caused the muscle itself to functionally tether the sphincter superiorly. This tethering of the peninsula flap accounted for not being able to use contractile muscle for the entire wrap. Instead, part of the distal tendon had to be used to complete the wrap in two cases. This was not a problem in the island flap design.

In addition to the above a number of other key features of the island flap design made it better suited for stoma sphincter construction. For example, the island flap design was more versatile in terms of positioning. It could be positioned perpendicular to the abdominal wall allowing the stoma to be delivered to the abdominal skin over the shortest distance without acute angulations. This feature minimizes the risk of distal bowel ischemia. On the other hand, the fact that the island flap was only tethered by its nervous attachments and the vascular pedicle could conceivably place traction on one of the innervating nerves when the muscle is electrically stimulated and contracts. However, one would expect that as the sphincter heals and forms attachments to the surrounding tissues it would become fixed in position making this concern more theoretical than real.

An advantage of the peninsula flap design over the island flap was its dual blood supply. However the disadvantage of the peninsula flap design was that it causes the sphincter to lie parallel to the abdominal wall thus requiring that a greater length of bowel be used to pass through the sphincter. This could increase the risk of distal bowel ischemia. In addition, the parallel orientation of the peninsula flap relative to the abdominal wall would cause two acute angulations in the bowel resulting in further potential risk of local ischemia and resultant stenosis. Finally stimulation of the peninsula flap sphincter would likely cause the entire contiguous muscle to contract resulting in distortion and upward displacement of the stoma. This could cause discomfort for the patient.

As with other striated, voluntary fast-twitch muscles, the rectus abdominis muscle fatigues rapidly if repeatedly stimulated. To apply this method clinically as in other dynamic myoplasty applications the RAM would have to be made fatigue-resistant in order to function as a stoma sphincter. This can be achieved by “training” the muscle as is done in cardiomyoplasty or graciloplasty,[32] in which case the latissimus dorsi and gracilis muscles are transformed from fatigue-prone to fatigue-resistant. We are currently conducting experiments in a dog model designed to define optimal electrical stimulation parameters that can be used to train the RAM flap stoma sphincter.

In summary, we have shown through detailed anatomical dissections that the RAM is ideally suited for constructing a stoma sphincter. The muscle is located in the appropriate anatomical location for stoma creation, it has a long vascular pedicle, and the preserved segmental intercostal innervation pattern allows the muscle to be tailored and mobilized in such a way to completely wrap a fecal stoma without significant muscle denervation. We found that the RAM island flap design is superior to the peninsula flap design for stoma sphincter construction. If in our future “functional” studies the RAM can be successfully trained to become fatigue-resistant, this technique could put the problem of stomal incontinence one step closer to being solved.

Acknowledgments

This project was supported in part by a Mason Rudd Grant from the Jewish Hospital Foundation, Louisville, KY, and grants from the “Prof. Michael-van Vloten fonds” and the “De Drie Lichten” Foundations in The Netherlands. We would like to thank Dr. Robert Acland for his guidance in the fresh tissue laboratory.

References

1 Cavina, E., Seccia, M., and Evangelista, G. Neo-sphincter and neo-stomy. New surgical views for myoelectric stimulated continence. A clinical experience. Preliminary report. *Am. J. Proctol. Gastroenterol. Colon Rectal Surg.* 33: 16, 1982.

2 Merrell, J.C., Russell, R.C., and Zook, E.G. Free microneurovascular gracilis muscle transfer in the dog for enterostomal sphincter construction and control: an experimental study. *Ann. Plast. Surg.* 17: 82, 1986.

3 Konsten, J., Baeten, C.G.M.I., van Mameren, H., Havenith, M.G., and Soeters, P.B. Feasibility of stoma continence using electrically stimulated rectus abdominis muscle in pigs. *Dis. Colon Rectum* 3: 247, 1993.

4 Hartrampf, C.R., Scheflan, M., and Black, P.W. Breast reconstruction with a transverse abdominal island flap. *Plast. Reconstr. Surg.* 69: 216, 1982.

5 Hallock, G.G. Intrathoracic application of the transverse rectus abdominis musculocutaneous flap. *Ann. Plast. Surg.* 29: 357, 1992.

6 Tobin, G.R., and Day, T.G. Vaginal and pelvic reconstruction with distally based rectus abdominis myocutaneous flaps. *Plast. Reconstr. Surg.* 81: 62, 1988.

7 Carlson, J.W., Carter, J.R., Saltzman, A.K., Carson, L.F., Fowler, J.M., and Twiggs, L.B. Gynecologic reconstruction with a rectus abdominis myocutaneous flap: an update. *Gynecol. Oncol.* 61: 364, 1996.

8 Horton, C.E., Sadove, R.C., Jordan, G.H., and Sagher, U. Use of the rectus abdominis muscle and fascia flap in reconstruction of epispadias/exstrophy. *Clin. Plast. Surg.* 15: 393, 1988.

9 Celayir, S., Kiliç, N., Eliçevik, M., and Büyükünal, C. Rectus abdominis muscle flap (RAMPF) technique for the management of bladder exstrophies: late clinical outcome and urodynamic findings. *Br. J. Urol.* 79: 276, 1997.

10 Bunkis, J.; Walton, R.L. and Mathes, S.J. The rectus abdominis free flap for lower extremity reconstruction. *Ann. Plast. Surg.* 11: 373, 1983.

11 Meland, N.B., Fisher, J., Irons, G.B., Wood, M.B., and Cooney, W.P. Experience with 80 rectus abdominis free-tissue transfers. *Plast. Reconstr. Surg.* 83: 481, 1989.

12 Hata, Y., Yano, K., Matsuka, K., Ito, O., Matsuda, H., and Hosokawa, K. Treatment of chronic facial palsy by transplantation of the neurovascularized free rectus abdominis muscle. *Plast. Reconstr. Surg.* 86: 1178, 1990.

13 Koshima, I., Tsuda, K., Hamanaka, T., and Moriguchi, T. One-stage reconstruction of established facial paralysis using a rectus abdominis muscle transfer. *Plast. Reconstr. Surg.* 99: 234, 1997.

14 Stevens, L., Badylak, S.F., Janas, W., Gray, M., Geddes, L.A., and Voorhees, W.D. A skeletal muscle ventricle made from rectus abdominis muscle in the dog. *J. Surg. Res.* 46: 84, 1989.

15 Milloy, F.J., Anson, B.J., and McAfee, D.K. The rectus abdominis muscle and the epigastric arteries. *Surg. Gynecol. Obstet.* 110: 293, 1960.

16 Boyd, J.B., Taylor, G.I., and Corlett, R. The vascular territories of the superior epigastric and the deep inferior epigastric systems. *Plast. Reconstr. Surg.* 73: 1, 1984.

17 Moon, H.K., and Taylor, G.I. The vascular anatomy of rectus abdominis musculocutaneous flaps based on the deep superior epigastric system. *Plast. Reconstr. Surg.* 82: 815, 1988.

18 Feller, A.M. Free TRAM, results and abdominal wall function. *Clin. Plast. Surg.* 1: 223, 1994.

19 Kroll, S.S., Schusterman, M.A., Reece, G.P., Miller, M.J., Robb, G., and Evans, G. Abdominal wall strength, bulging and hernia after TRAM flap breast reconstruction. *Plast. Reconstr. Surg.* 96: 616, 1995.

20 Watterson, P.A., Bostwick, J. III, Hester, T.R. Jr., Bried, J.T., and Taylor, G.I. TRAM flap anatomy correlated with a 10-year clinical experience with 556 patients. *Plast. Reconstr. Surg.* 95: 1185, 1995.

21 Allen, R.J., and Treece, P. Deep inferior epigastric perforator flap for breast reconstruction. *Ann. Plast. Surg.* 32: 32, 1994.

22 Blondeel, Ph.N., Vanderstraeten, G.G., Monstrey, S.J., Van Landuyt, K., Tonnard, P., Lysens, R., Boeckx, W.D., and Matton G. The donor site morbidity of free DIEP flaps and free TRAM flaps for breast reconstruction. *Br. J. Plast. Surg.* 50: 322, 1997.

23 Geishauser, M., Staudenmaier, R.W. and Biemer, E. Donor-site morbidity of the segmental rectus abdominis muscle flap. *Br. J. Plast. Surg.* 51: 603, 1998.

24 Hammond, D.C., Larson, D.L., Severinac, R.N., and Marcias, M. Rectus abdominis muscle innervation: implications for TRAM flap elevation. *Plast. Reconstr. Surg.* 96: 105, 1995.

25 Cullen, T.S., and Brödel, M. Lesions of the rectus abdominis muscle simulating an acute intra-abdominal condition: I. Anatomy of the rectus muscle. *Bull. Johns Hopkins Hosp.* 61: 295, 1937.

26 Bishop, W.E., Carr, B.W., Anson, B.J., and Ashley, F.L. The parietal intermuscular plexus of the thoracic nerves. *Quart. Bull. N.U.M.S.* 17: 209, 1943.

27 Rouvière, H. *Anatomie humaine descriptive et topographique*, Vol. 2. Paris: Masson, 1959.

28 Testut, L. *Traité d'anatomie humaine*, Vol. 3. Paris: G. Doin, 1949.

29 Duchateau, J., Declety, A., and Lejour, M. Innervation of the rectus abdominis muscle: Implications for rectus flaps. *Plast. Reconstr. Surg.* 82: 223, 1988.

30 Gosling, J.A., Harris, P.F., Humpherson, J.R., Whitemore, I., and Willan, P.L. *Atlas of human Anatomy with Integrated Text from Manchester University Department of Anatomy*. London: Gower Medical, 1985.

31 Hollinshead, W.H. *Anatomy for Surgeons*, Vol. 2. New York: Hoeber, 1956.

32 Grandjean, P., Acker, M., Madoff, R., Williams, N.S., Woloszko, J., and Kantor, C. Dynamic myoplasty: Surgical transfer and stimulation of skeletal muscle for functional substitution or enhancement. *J. Rehabil. Res. Dev.* 33: 133, 1996.